UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE MYLAN, N.V. SECURITIES LITIGATION

Master File No. 2:20-cv-00955-NR

CONSOLIDATED CLASS ACTION COMPLAINT

COMPLAINT-CLASS ACTION

DEMAND FOR JURY TRIAL

Hon. J. Nicholas Ranjan

TABLE OF CONTENTS

GLOSSARY OF KEY TERMS i

I. INTRODUCTION 1

II. JURISDICTION AND VENUE 9

III. PARTIES 10

A. Plaintiff 10

B. Defendants 10

1. The Corporate Defendant 10

2. The Officer Defendants 11

IV. DEFENDANTS' FRAUDULENT SCHEME 12

A. Background On Mylan 12

B. Defendant Malik Joins Mylan 14

C. The FDA's CGMP And Data Integrity Regulations 15

1. Quality Control And Data Integrity Were Central To Mylan's Business 15

2. FDA Enforcement Of CGMP And Data Integrity Requirements 18

3. FDA Regulatory Actions Arising From CGMP And Data Integrity Violations 19

D. Prior To The Class Period, Price Erosion In Mylan's Core Generics Business Placed Enormous Pressure On The Company To Sustain Morgantown's Massive Volume 22

E. Throughout The Class Period, Defendants Misled Investors About Mylan's Quality Controls and Operating Capacity 23

1. Defendants Assured Investors That Mylan's Quality Assurance Processes Were Robust 23

2. Defendants Touted Mylan's "Broad" Operating Capacity And Assured Investors That The Company Did Not Need To Downsize Its Generics Portfolio 27

F. In Truth, Mylan's Manufacturing Facilities, Including Its Key Morgantown Plant, Were Rife With Serious CGMP And Data Integrity Failures 28

2. Prior To The Start Of The Class Period, Defendants Received Numerous Warnings Of CGMP And Data Integrity Failures At Mylan, Including At Morgantown 30

3. The Nashik Form 483 32

4. The FDA's Surprise Inspection Of Morgantown In 2016 32

5. Mylan Former Employees Corroborate The FDA's Findings 37

6. The Morgantown Facility's Enormous Volume Drove Mylan's Violations Of CGMP Standards 45

7. Following The 2016 Morgantown Inspection, Defendant Malik Privately Met With The FDA To Fend Off Further Agency Action 50

8. Defendants Create A "Façade of Documents" Hoping To Appease The FDA 54

9. During Its March 2018 Morgantown Inspection, The FDA Found That Mylan's CGMP And Data Integrity Failures Were Still Widespread 59

10. Following The FDA's 2018 Inspection, Mylan Was Forced To Halt Production At Morgantown, Dramatically Reduce Its Portfolio, And Implement Expensive Remedial Measures 63

V. THE TRUTH EMERGES 64

A. June 27, 2018: Disclosure Of Morgantown Investigation And 2018 Form 483 64

B. August 8, 2018: Disclosure Of "Restructuring and Remediation Program In Morgantown" 66

C. November 9, 2018: FDA Warning Letter Concerning CGMP Violations At Morgantown 69

D. February 26, 2019: Disclosure of 18% Decrease In Net Sales Due To Morgantown Restructuring 73

E. May 7, 2019: Disclosure Of Q1 2019 Loss Due To Morgantown Restructuring 75

VI. SUMMARY OF ALLEGATIONS THAT DEFENDANTS KNOWINGLY OR RECKLESSLY MISLED INVESTORS 77

VII. DEFENDANTS' FALSE AND MISLEADING STATEMENTS 90

A. Defendants' False And Misleading Statements Concerning Quality Assurance And Mylan's Attempts To Comply With CGMP And Data Integrity Standards 91

1. Defendants' False And Misleading Statements Published On The Mylan Website Throughout The Class Period 91

2. Defendants' False And Misleading Statements Made In SEC Filings And On Investor Conference Calls 96

B. Defendants' False And Misleading Statements Concerning Mylan's "Broad" Operating Capacity And Asserting That The Company Did Not Need To Downsize Its Generics Portfolio 111

C. Defendants' False And Misleading Statements Concerning The Impact On Mylan's Business Of The FDA's Regulatory Actions And The Company's Subsequent Remediation Efforts 118

VIII. LOSS CAUSATION 121

IX. CLASS ACTION ALLEGATIONS 123

X. PRESUMPTION OF RELIANCE 125

XI. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR 126

XII. CLAIMS BROUGHT PURSUANT TO THE EXCHANGE ACT 126

FIRST CLAIM FOR RELIEF 126

For Violation of Section 10(b) of the Exchange Act and SEC Rule 10b-5 Thereunder (Against All Defendants) 126

SECOND CLAIM FOR RELIEF 128

For Violation of Section 20(a) of the Exchange Act (Against the Officer Defendants) 128

XIII. PRAYER FOR RELIEF 128

XIV. JURY DEMAND 129

GLOSSARY OF KEY TERMS

2016 Form 483	Form 483 issued to Mylan on November 18, 2016 regarding its Morgantown facility
2018 Form 483	Form 483 issued to Mylan on April 12, 2018 regarding its Morgantown facility
API	Active pharmaceutical ingredient
Bottle of Lies	*Bottle of Lies: The Inside Story of the Generic Drug Boom* by Katherine Eban, published in May 2019
CGMP	Current Good Manufacturing Practices: regulations enforced by the FDA, which provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities.
Data Integrity	Refers to the FDA's requirement that all data recorded and reported be complete, consistent, and accurate, as well as attributable, legible, contemporaneously recorded, original or a true copy
Eban	Katherine Eban, investigative journalist and author of *Bottle of Lies: The Inside Story of the Generic Drug Boom*
Form 483	A citation issued by the FDA to a drug manufacturer at the conclusion of an inspection, which notifies the company's management of objectionable conditions the investigator has observed
Nashik Form 483	Form 483 issued to Mylan in late 2016 regarding its Nashik, India facility, following a nine-day inspection of the plant
OOS	Out-of-specification test results
Warning Letter	A notification to a drug manufacturer that the FDA has found that the manufacturer has significantly violated FDA regulations

Lead Plaintiff the Public Employees' Retirement System of Mississippi ("MissPERS"), by and through its counsel, brings this action individually and on behalf of all persons and entities who purchased or otherwise acquired the publicly traded common stock of Mylan, N.V. ("Mylan" or the "Company") between February 16, 2016 and May 7, 2019, inclusive (the "Class Period").

Lead Plaintiff alleges the following upon information and belief, except as to those allegations concerning Lead Plaintiff, which Lead Plaintiff alleges upon personal knowledge. Lead Plaintiff's information and belief is based upon Lead Counsel's investigation, which included the review and analysis of: (i) Mylan's regulatory filings with the U.S. Securities and Exchange Commission (the "SEC"); (ii) Mylan's press releases and public statements; (iii) analyst reports concerning Mylan; (iv) interviews with former employees of Mylan, industry professionals, and other knowledgeable persons; and (v) additional public information regarding the Company and its industry. Lead Counsel's investigation into the factual allegations contained in this Complaint is continuing, and many of the relevant facts are known only by Defendants or are exclusively within their custody or control. Lead Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth in this Complaint after a reasonable opportunity for further investigation or discovery.

I. INTRODUCTION

1. This case arises from Defendants' concealment of Mylan's systemic and egregious violations of key FDA regulations governing product quality and safety, including at the Company's flagship drug manufacturing facility in Morgantown, West Virginia. Knowing that compliance with these regulations was critically important to the market, Mylan repeatedly assured investors that the Company implemented "advanced" product quality control processes that met or exceeded regulatory requirements and conducted rigorous "reviews of all products, start to finish." Moreover, in direct response to analyst questions, Mylan's senior executives, including

CEO Heather Bresch and President Rajiv Malik, distinguished Mylan from its competitors based on the Company's ability to produce an enormous volume of drugs, all while "meeting or exceeding" "stringent" quality standards. These statements were false. As multiple whistleblowers, Company employees, and the FDA all warned Mylan during the Class Period, the Company's single-minded focus on maximizing production led Mylan to sacrifice quality and safety for speed, exposing it to regulatory sanctions, extremely costly business disruptions, and expensive remediation. Indeed, the FDA warned Defendants in 2016 that Morgantown was rife with severe violations of FDA-mandated quality and safety standards, including a host of improper conduct designed to bypass the very quality systems and controls Defendants repeatedly touted. At the end of the Class Period, Mylan finally admitted the truth: its overwhelming focus on generating massive volumes of drugs was unsustainable, and it had to halt production at Morgantown and dramatically reduce Mylan's generics portfolio going forward.

2. Mylan is one of the largest generic drug manufacturers in the country. The FDA regulates Mylan through quality-control regulations called Current Good Manufacturing Practices ("CGMP"). "Data integrity" requirements, which are designed to ensure that quality and safety testing is complete, accurate, and free from manipulation, are a core component of CGMP. As Mylan itself repeatedly acknowledged, compliance with CGMP regulations, including data integrity requirements, was critical to the Company's business and profitability. If the FDA discovers serious CGMP violations, it may effectively freeze a drug manufacturer's operations, require recalls, and order extensive remedial action that may involve extensive costs and prolonged disruptions to production.

3. Given the importance of product quality and regulatory compliance, Defendants issued a host of statements throughout the Class Period describing Mylan's robust and

comprehensive quality control processes. Defendants stated, for instance, that Mylan's quality teams "conduct reviews of all products, start to finish" and that the Company "uses advanced testing and monitoring systems to assure product adheres to" regulatory and industry standards. Defendants also claimed that "each" of Mylan's manufacturing "site[s] adheres to stringent quality standards" and that each of the steps in Mylan's quality control process is "wrapped in a series of reviews, designed to meet or exceed" regulatory standards. Defendant Malik stressed to investors that Mylan was characterized by a "deliberate and thorough approach to ensure sustainable quality across our entire network of facilities." Defendants also assured investors that Mylan had established management-level oversight to ensure vigilant enforcement of the Company's quality control standards, including a "Quality Council program," which "provides management with clear, quantitative data" on CGMP compliance.

4. Defendants Bresch and Malik also repeatedly touted the fact that Mylan could maintain these strict quality standards while maintaining, by far, the industry's largest production volumes and an enormous portfolio of different drugs. Repeatedly, and in direct response to analyst questions, Defendants told investors that Mylan's vast operational capacity gave the Company a unique ability to withstand the generic drug price erosion that was plaguing the industry. According to Bresch, as competitors with supposedly less rigorous quality standards than Mylan struggled to meet CGMP requirements, Mylan leveraged its high-quality manufacturing capacity to attract customers and take advantage of market shortages.

5. In truth, and contrary to Defendants' statements, Mylan's manufacturing facilities, including its flagship Morgantown facility—the cornerstone of its North American business—were rife with systemic, egregious, and long-standing CGMP and data integrity failures. These

failures exposed the Company to serious regulatory penalties, costly production disruptions, and expensive remediation.

6. In September 2015, before the Class Period began, a former Mylan employee turned whistleblower disclosed to the FDA that, under the direct leadership of Defendant Malik, Mylan employees had been manipulating drug test results to achieve passing quality control results. The whistleblower told the FDA that Mylan employees were deliberately and routinely corrupting testing data by, among other techniques, intentionally crashing Mylan testing computers to evade FDA detection.

7. On November 7, 2016, after receiving the whistleblower complaint, inspectors arrived unannounced at Mylan's Morgantown facility to conduct an 11-day investigation. Morgantown was Mylan's largest, and one of its most significant, manufacturing facilities during the Class Period. The Morgantown plant was critical to the Company's largest business segment—its North American business—and manufactured approximately 85% of the oral solid doses of medicine Mylan sold in the United Stated during the Class Period.

8. When they arrived at Morgantown, the investigators discovered the Company was systematically using a host of suspect data practices to avoid reporting failing quality control testing results that could trigger lengthy production delays or even product recalls. The FDA found thousands of random files containing what appeared to be forbidden exploratory tests, a tactic some drug-makers have used to prevent quality failures from coming to light. The FDA also found bins full of shredded documents, including quality-control records, in parts of the facility where such documentation is supposed to be preserved. The FDA suspected Mylan laboratory staff had recorded passing scores on drugs that originally fell short of U.S. quality standards. The FDA warned Defendants that Mylan routinely engaged in a highly improper practice known as

"testing into compliance," which involves repeatedly retesting drug products that had failed quality testing in order to achieve passing results—and is specifically prohibited under FDA guidance. As a result, on November 18, 2016, the FDA privately issued to Mylan a 23-page citation detailing these findings. The FDA's extensive and thorough criticisms put Mylan on notice that the Company would need to immediately begin extensive remediation, including significantly reducing Morgantown's unrealistic production volumes, and that it faced a serious risk of further adverse regulatory action. Nevertheless, Former Employees reported that Defendant Malik continued to insist on cuts to Morgantown's quality budget, rather than the material expansion of the budget called for by the FDA's findings.

9. Even after receiving the FDA's scathing inspection report—called a Form 483—Defendants continued to receive clear and direct warnings that Morgantown suffered from severe quality control issues. Indeed, in April 2017, shortly after the FDA issued its Form 483, Defendant Malik attended a private meeting with the FDA. At that meeting, agency officials directly told Defendant Malik that they were "stunned" by Mylan's "egregious" violations, which they said led the agency to question whether the Company was being "transparent at all of its sites." Moreover, during the Class Period, Mylan was forced to recall numerous drug products manufactured at Morgantown, including drugs cited in the FDA's 2016 Form 483. Nevertheless, Defendants continued to misleadingly tout Mylan's "advanced" and comprehensive quality control processes and the Company's commitment to CGMP compliance.

10. On April 3, 2017, Mylan received a warning letter from the FDA concerning one of its India plants, detailing nearly identical data corruption issues and other violations that paralleled those described in the FDA's November 2016 Form 483 directed to Mylan's Morgantown plant. A full month later, on May 10, 2017, during Mylan's first quarter 2017

earnings conference call, Defendant Malik downplayed the letter as reflecting a discrete set of one-off technical issues that were confined to just one of Mylan's plants. Defendant Malik stated that Mylan was "dedicated to continually enhancing our systems and processes, with a deliberate and thorough approach to ensure sustainable quality across our entire network of facilities, working closely with FDA to resolve any issues that come our way." Indeed, Defendant Malik boasted that inspections of Mylan's remaining facilities had all been successful. Defendant Malik failed to disclose the Form 483 issued to the Company's far more significant Morgantown facility or the financial and regulatory risk it entailed, despite the fact that just weeks earlier FDA officials told Defendant Malik directly that Morgantown's failures were "egregious" and raised serious questions about the integrity of the Company's products.

11. On April 20, 2018, Mylan announced it would be restructuring its Morgantown plant, including by terminating 500 employees. Mylan stated that the "Morgantown plant needed to be right-sized to be less complex" due to general "industry" changes. While Mylan's statement asserted that these changes are "consistent with discussions we are having with the [FDA]," Mylan did not elaborate on the substance of those discussions or indicate that the restructuring was related to the significant violations identified by the FDA.

12. Investors did not know that beginning in early 2018, a whistleblower inside the Morgantown facility privately told the FDA that, instead of working to remedy problems identified in the 2016 Form 483, Mylan was more focused on creating a "façade of documents" to fend off the agency and, as a result, product quality was continuing to deteriorate rather than improve. The whistleblower further told the FDA that Mylan had developed an "embedded culture" of fraud. In response, the FDA conducted another surprise inspection of Morgantown in March 2018, and its findings corroborated the whistleblower's report.

13. Following its inspection, the FDA issued Mylan the second Form 483 related to Morgantown in less than two years, citing the same egregious CGMP and data integrity violations about which Defendants and other members of Mylan's senior leadership had been repeatedly warned, including in Morgantown's 2016 Form 483. Among other things, the FDA found that Mylan's improper practice of invalidating failing results and re-testing drug products without adequate investigation was still widespread and that Mylan's "senior management" had failed to exercise appropriate quality control oversight.[1] In a subsequent warning letter issued to Mylan, the FDA made clear that the agency had repeatedly warned the Company its practice of "testing into compliance" was improper, stating that "the unjustified invalidation of failing test results is a repeat violation." Moreover, the FDA emphasized that the seriousness, pervasiveness, and duration of the violations left little doubt that Mylan's senior management was directly responsible: "These repeated failures at multiple sites demonstrate that Mylan's management oversight and control over the manufacture of drugs is inadequate . . . . Your executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance."

14. Significantly, following the 2018 inspection, Defendants admitted in private correspondence with the FDA that "the large volume of doses and products within the Morgantown portfolio . . . inhibited [Mylan's] ability to achieve the high level of control over our manufacturing processes that we expect."

15. Accordingly, after the FDA's 2018 Morgantown inspection, Mylan was finally compelled to take meaningful remedial measures, as it should have done even before the start of the Class Period. First, Mylan was forced to halt production at the facility in order to prevent the release of adulterated products. Second, Mylan was forced to dramatically reduce Morgantown's

[1] Unless otherwise noted, all emphasis is added throughout this Complaint.

overwhelming production volume. Third, Mylan was forced to implement extensive remedial measures under consultant supervision. As a result of these steps, Mylan's sales declined, and expenses increased, respectively, by at least hundreds of millions of dollars.

16. Just before the market closed on June 27, 2018, *Bloomberg* leaked the news of the 2018 Form 483, including the fact that the FDA had made thirteen separate observations of deficiencies related to the Company's flagship plant. On this news, Mylan's share price fell $1.12 per share, or approximately 3%, from $37.45 per share to $36.33 per share. In an effort to spin the story to quell investor concern, Mylan issued a press release on June 28, 2018 that downplayed the Morgantown inspection. Defendants failed to disclose that the FDA's inspection had forced Mylan to halt production at Morgantown, significantly reduce the Company's generics portfolio, and had materially increased operating costs.

17. Then, on August 8, 2018, during Mylan's first earnings conference call since announcing the FDA's Morgantown investigation, Defendant Malik explained that Mylan had "undertaken a restructuring and remediation program in Morgantown" that included a "discontinuation of a number of products" and would have a "negative impact on production levels, product supply and operations." On this news, Mylan's share price fell $2.62 per share, or approximately 7%, from $39.23 per share to $36.61 per share. Nevertheless, Mylan executives assured investors that the Morgantown restructuring "impact is temporary" and that Mylan's "profitability levels are sustainable."

18. Next, on February 26, 2019 during Mylan's fourth quarter and fiscal year 2018 earnings conference call, Mylan stunned investors when the Company announced an 18% decrease in North American net sales from the prior year, attributing this shortfall, in part, to its Morgantown

restructuring, which included the discontinuation of almost 250 products. On this news, Mylan's share price fell $4.61 per share, or approximately 15%, from $30.62 per share to $26.01 per share.

19. Finally, on May 7, 2019, Mylan reported a surprise loss for the first quarter of 2019 due, in part, to additional costs associated with the Morgantown restructuring. Mylan reported that its revenues and earnings-per-share were down year-over-year by 7% and 15%, respectively, as Mylan discontinued manufacturing certain products in the Morgantown facility, and that its quarterly adjusted free cash flow was severely lacking, now matching its 2015 levels. Defendant Bresch attributed the cash flow swing to, among other factors, "the Morgantown remediation" and disclosed an additional $70 million in expenses tied to the facility's restructuring. On this news, Mylan's share price fell $6.73 per share, or approximately 24%, from $28.26 per share to $21.53 per share.

20. As the relevant truth about Mylan's widespread CGMP and data integrity violations was finally revealed to investors, Mylan's stock price declined precipitously, wiping out billions in shareholder value.

II. JURISDICTION AND VENUE

21. The claims asserted in this Complaint arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and SEC Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

22. This Court has jurisdiction over the claims asserted in this Complaint pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa), and 28 U.S.C. §§ 1331.

23. Venue is proper in this District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa), and 28 U.S.C. § 1391(b). Mylan maintains its corporate headquarters in Canonsburg, Pennsylvania, which is situated in this District, conducts substantial business in this District, and many of the acts and conduct that constitute the violations of law complained of in

this Complaint, including the preparation and dissemination to the public of materially false and misleading information, occurred in this District.

24. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

A. Plaintiff

25. Lead Plaintiff MissPERS is a pension fund established for the benefit of the current and retired public employees of the State of Mississippi. Lead Plaintiff is responsible for the retirement income of employees of the State, including current and retired employees of the State's public-school districts, municipalities, counties, community colleges, state universities, libraries, and water districts. Lead Plaintiff provides benefits to over 75,000 retirees, manages over $28 billion in assets for its beneficiaries, and is responsible for providing retirement benefits to more than 250,000 current public employees. As set forth in the Declaration filed at ECF No. 1, MissPERS purchased Mylan common stock at artificially inflated prices during the Class Period and suffered damages as a result of the violations of the securities laws alleged in this Complaint.

B. Defendants

1. The Corporate Defendant

26. Defendant Mylan is headquartered at 1000 Mylan Boulevard, Canonsburg, Pennsylvania. Mylan is the second largest generic drug manufacturer in the world with roughly 55 manufacturing and research and development facilities globally. Mylan's common stock is listed and trades on the NASDAQ, an efficient market, under the ticker symbol "MYL." As of

May 7, 2019 (the end of the Class Period), Mylan had over 514 million shares of stock outstanding, owned by at least thousands of investors.

2. The Officer Defendants

27. Defendant Heather Bresch has been Mylan's CEO since January 1, 2012. Among other positions at Mylan, Bresch has served as President, Chief Operating Officer, and Chief Integration Officer. Defendant Bresch has been a member of Mylan's Board of Directors (the "Board") since 2011. During the Class Period, Defendant Bresch signed Mylan's Forms 10-K filed with the SEC on February 16, 2016, March 1, 2017, and March 1, 2018, as well as the Company's proxy statement filed on May 24, 2017, among other SEC filings.

28. Defendant Rajiv Malik joined Mylan in January 2007 and has been Mylan's President since January 1, 2012. In this role, Defendant Malik is responsible for the day-to-day operations of Mylan, including the Company's Commercial, Scientific Affairs, Manufacturing, Supply Chain, and Quality divisions. Defendant Malik has been a member of the Board since 2013. Prior to joining Mylan, Malik served as the CEO of Matrix Laboratories from 2005 to 2007, when Mylan acquired Matrix Labs. Prior to 2005, Defendant Malik served in leadership roles at Sandoz, the German pharmaceutical giant, and Ranbaxy, an Indian pharmaceutical company. At Ranbaxy, Defendant Malik began his career in generics research and development and rose through the ranks over a seventeen-year tenure to become the company's Head of Formulation Development and Regulatory Affairs. During the Class Period, Defendant Malik signed Mylan's Forms 10-K filed with the SEC on February 16, 2016, March 1, 2017, and March 1, 2018, among other SEC filings.

29. Defendant Kenneth "Ken" Parks joined Mylan in June 2016 as the Company's Chief Financial Officer ("CFO"). During the Class Period, Defendant Parks signed Mylan's Forms 10-K filed with the SEC on March 1, 2017 and March 1, 2018, among other SEC filings.

30. Defendants Mylan, Bresch, Malik, and Parks are referred to in this Complaint as "Defendants." Defendants Bresch, Malik, and Parks are collectively referred to in this Complaint as the "Officer Defendants."

IV. DEFENDANTS' FRAUDULENT SCHEME

A. Background On Mylan

31. As of the beginning of the Class Period, Mylan was the second-largest generic drug manufacturer in the world. During the Class Period, Defendants repeatedly claimed that Mylan's generic drugs filled one out of every 13 prescriptions dispensed in the United States.

32. A generic drug is a pharmaceutical containing the same chemical properties and substances as a patented brand-name drug, which can be sold after the branded drug's patent expires. Because the active chemicals and substances of generic drugs are the same as the original drugs, generics are believed to be equivalent in performance, strength, safety, and effectiveness to their brand-name counterparts. Generic drugs may differ, however, in manufacturing process, formulation, appearance, or packaging.

33. Generic drugs are inexpensive because the companies that manufacture them rely on research already done by brand-name pharmaceutical companies, saving hundreds of millions of dollars in research and development costs. To receive FDA approval, the generic drug maker must prove that its generic drug works in the same manner as its branded counterpart.

34. Mylan operates 16 manufacturing, distribution, and administrative facilities in the United States and Puerto Rico. The Company's Morgantown, West Virginia campus is Mylan's largest and most significant facility in the world; in fact, it is one of the largest pharmaceutical manufacturing facilities in the entire United States. The Morgantown facility spans over 22 acres, employs over 3,000 people, and includes Mylan's research and development center and manufacturing plant. In a January 2019 report, Leerink securities analysts noted that in 2016, the

Morgantown facility manufactured approximately 85% of the oral solid doses (e.g., tablets and gel capsules) of medicine sold by Mylan in the United States.

35. For decades after its founding in 1961, Mylan had a sterling reputation with the public, including investors, for quality, transparency, and compliance with good manufacturing practices. As Katherine Eban, investigative journalist and author of *Bottle of Lies: The Inside Story of the Generic Drug Boom*, describes, Mylan's founder Mike Puskar articulated the Company's ethos as, "Do it right, or don't do it at all." In 2009, Mylan sued the *Pittsburgh Post-Gazette* after the newspaper published an article alleging data fraud at the Morgantown plant, including the practice of "crashing files," described in more detail below. In response, Mylan vigorously denied the newspaper's allegations and sued the *Post-Gazette* for misappropriation of trade secrets and libel. Recognizing the significance of the newspaper's reporting, Mylan's complaint alleged that the suggestion of data fraud at its flagship facility "harm[ed] . . . Mylan and its shareholders" by causing decreases in its stock price and market capitalization, and would "adversely affect" its business reputation; "impugn the integrity" of its procedures and personnel; and "threaten [its] current and prospective business relationships." Mylan also alleged that its business depended on compliance with FDA regulations, claiming that its quality and compliance procedures "enable it to maintain a competitive advantage that has made it a leading manufacturer of generic pharmaceuticals."

36. Analysts credited the Company's claims of transparency and compliance. As J.P. Morgan wrote in 2009, investors viewed Mylan as having "one of the strongest manufacturing track records in the generics industry and a reputation for the high quality of its product."

37. As set forth below, by the start of the Class Period, and under Defendants Bresch's and Malik's leadership, Mylan had utterly abandoned high-quality manufacturing in favor of

massive drug production volumes. However, notwithstanding the Company's extreme departure from its prior focus on quality, Defendants maintained Mylan's façade of quality control excellence through repeated false and misleading statements touting the Company's quality assurance standards and processes.

B. Defendant Malik Joins Mylan

38. In the 2000s, Mylan began to expand significantly through acquisitions of Indian companies, gaining access to the Indian and Chinese markets and acquiring significant manufacturing facilities.

39. In late 2006, Mylan announced its acquisition of Matrix Laboratories, a publicly traded company based in India that had served as one of Mylan's major active pharmaceutical ingredient ("API") suppliers. As part of the transaction, Mylan installed Defendant Malik—Matrix's then-CEO—as its Executive Vice President for Global Technical Operations.

40. Before joining Matrix, Defendant Malik had spent seventeen years at Ranbaxy, an Indian generic drug manufacturer, where he rose through the ranks to become the Head of both Formulation Development (i.e., research and development) and Regulatory Affairs. During Defendant Malik's tenure and shortly after he left, Ranbaxy was the site of what *Bloomberg* later called "one of the most dramatic examples of data manipulation in the history of the generics business." As detailed in *Bottle of Lies*, a Ranbaxy employee who worked in data integrity blew the whistle on Ranbaxy after discovering that the company had "lied to regulators, falsified data, and endangered patient safety." The Ranbaxy whistleblower discovered that, among other violations, Ranbaxy's scientists routinely faked dissolution studies and substituted lower-purity ingredients for higher ones to reduce costs. Sometimes, the company simply invented data. As Eban describes, "There was little effort to conceal this method of doing business. It was common knowledge." The Ranbaxy whistleblower ultimately resigned and reported his findings to the

FDA, which conducted an armed raid on the company's New Jersey headquarters. While Defendant Malik had left Ranbaxy by the time of the FDA raid, according to *Bottle of Lies*, the practices reported by the whistleblower were widespread throughout Malik's tenure.

41. As reported in *Bottle of Lies*, Defendant Malik took charge of overseeing Mylan's "swelling operation in India, where the company would soon grow to have twenty-five of its forty global facilities and over half of its 30,000 employees." Defendant Malik emphasized competition between Mylan's research and development teams in Morgantown and India, leading the Company in three years to triple the number of drug applications it submitted to the FDA and to double approvals.

42. Publicly, Defendant Malik described his mission at Mylan as one to ensure that Mylan did not meet the same fate as Ranbaxy, which Defendant Malik later described as "a beautiful story gone sad." As such, Defendant Malik knew that failure to comply with the CGMP and data integrity regulations governing generic drug manufacturers—as described in more detail below—could expose the Company to highly adverse consequences, as discussed below. Punctilious regulatory compliance and quality control, however, were incompatible with Defendant Malik's "laser-like focus to bring drugs to market," and his drive to make Mylan "a hothouse of productivity."

C. The FDA's CGMP And Data Integrity Regulations

1. Quality Control And Data Integrity Were Central To Mylan's Business

43. As a generic drug maker, Mylan is required to comply with specific FDA quality-control regulations, CGMP, relating to the development and manufacturing of its drugs. Mylan's business, reputation, and ability to manufacture and sell its drugs depended on its strict compliance with CGMP and data integrity standards. Drug makers must certify compliance with CGMP when

seeking approval of new drugs, including generic drugs, and must maintain compliance in order to continue to market and sell them. Indeed, under federal law, a drug is "deemed adulterated," i.e., its strength, quality, or purity is not as labeled, if "the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice." 21 U.S.C. § 351(a)(2)(B).

44. The FDA principally relies on these process-based regulations because it cannot test all finished drugs or ingredients distributed in the United States. As FDA guidance explains, the agency views CGMP as the "main regulatory standard for ensuring pharmaceutical quality." CGMP standards require drug manufacturers to establish strong quality management systems and robust operating procedures, detect and investigate all product quality deviations, and maintain reliable testing laboratories. These requirements are codified, in part, at 21 C.F.R. Pt. 11, 21 C.F.R. §§ 210 and 211, and additional guidance issued by the agency. The regulations are designed to ensure a company's drug product "meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." 21 C.F.R. § 210.1.

45. The FDA must also necessarily rely on testing and quality control data generated and furnished by Mylan and other pharmaceutical companies in making important public health decisions about both proposed new drugs and drugs currently on the market. Accordingly, "data integrity" requirements are a key element of the FDA's CGMP regulations.

46. The FDA's data integrity requirements are designed to ensure that testing data is complete, consistent, accurate, and free from potential manipulation. These data integrity regulations require, for example, that drug manufacturers record the results of all mandatory

quality testing of both drugs and equipment, "thoroughly investigate[]" any results that fail to "meet any of its specifications," and compile a record of that investigation. 21 C.F.R. §§ 211.100; 211.192 ("Any unexplained discrepancy . . . or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated").

47. Moreover, manufacturers must thoroughly document and track all steps they take during production, including all quality testing performed and results obtained. For instance, the FDA requires that "production procedures," including quality testing, must be written and approved by a managerial "quality unit"; that production procedures "be documented at the time of performance," including "complete records of all tests performed"; and that "[a]ny deviation from the written procedures shall be recorded and justified." 21 C.F.R. §§ 211.100, 212.192.

48. The FDA insists on rigorous data integrity requirements because data integrity is essential to ensure that test data is neither lost nor manipulated and, therefore, that drugs are safe and effective. As FDA guidance explains, "Data integrity is critical throughout the CGMP data life cycle, including in the creation, modification, processing, maintenance, archival, retrieval, transmission, and disposition of data after the record's retention period ends."

49. The FDA's core CGMP requirement to "thoroughly investigate" failing or anomalous quality testing results prohibits "testing into compliance." "Testing into compliance" refers to the improper practice of successively re-testing drug products that have failed analytical testing and inspection until passing results are obtained, without investigating, or even reporting, the failing results. The FDA has long warned manufacturers that "testing into compliance" is a particularly serious violation of CGMP regulations and the scientific standards essential to ensuring consumer safety.

50. For instance, the agency issued guidance in 2006, explaining that "FDA inspections have revealed that some firms use a strategy of repeated testing until a passing result is obtained, then disregarding the OOS results without scientific justification. This practice of 'testing into compliance' is unscientific and objectionable under CGMPs." The guidance further lays out strict rules for performing quality testing, "The maximum number of retests to be performed on a sample should be specified in advance in a written standard operating procedure (SOP) . . . . If the results are unsatisfactory at this point, the batch is suspect and must be rejected or held pending further investigation (§ 211.165(f))." Importantly, "[t]he number of retests should not be adjusted depending on the results obtained." Finally, "[a]ny deviation from this SOP should be rare and done in accordance with § 211.160(a), which states that any deviations from written specifications, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified. In such cases, before starting additional retesting, a protocol should be prepared (subject to approval by the [management-level quality control unit]) that describes the additional testing to be performed and specifies the scientific and/or technical handling of the data."

51. Despite the fact that "testing into compliance," constitutes a serious data integrity violation, as discussed below, it was widespread at Mylan, including at Morgantown, throughout the Class Period, even after the FDA explicitly warned Defendants in 2016 that the practice was pervasive at the facility.

2. FDA Enforcement Of CGMP And Data Integrity Requirements

52. The FDA enforces CGMP and data integrity requirements through periodic inspections of drug makers' manufacturing and packaging facilities. At the conclusion of an inspection, holds a close-out meeting with company management and shares its observations. If the FDA inspectors identify CGMP violations, the FDA will privately provide the drug maker with a form entitled "Inspectional Observations," known as an FDA Form 483. The FDA will issue

these Forms 483 when, "in the investigator's 'judgment', conditions or practices observed, indicate that any food, drug, device or cosmetic have been adulterated or are being prepared, packed or held under conditions whereby they may become adulterated or rendered injurious to health." Generally, the FDA does not publish, or announce the issuance of, Forms 483—only select Forms 483 are posted to the FDA website. The company has an obligation to respond to the FDA's observations within fifteen business days with a root cause analysis, impact assessment, and a set of corrective and preventative actions.

53. Following an inspection and issuance of a Form 483, the FDA may also issue a warning letter to a drug manufacturer if, among other things, it believes the manufacturer has failed to take adequate corrective action. Unlike Forms 483, the FDA regularly publishes warning letters on its website.

3. FDA Regulatory Actions Arising From CGMP And Data Integrity Violations

54. The FDA has emphasized that companies that violate CGMP and data integrity requirements face severe sanctions. Indeed, FDA guidance explains that "data integrity-related CGMP violations have led to numerous regulatory actions, including warning letters, import alerts, and consent decrees." In particular, the FDA has noted that it "rel[ies] on firms to do the right thing when [the] FDA is not present," and data integrity problems "break trust" between an agency and a regulated entity.[2]

55. If the FDA discovers serious, pervasive, and repeat CGMP and data integrity violations, the FDA may order the Company to take extensive remedial action that could require

[2] Capt. Sharon K. Pederson (Thoma), PharmD, National Expert of Pharmaceutical Inspections, FDA, Medical Products and Tobacco Program Operations Branch, Data Integrity Issues & Concerns (Feb. 6, 2017).

the company to cease operations, in whole or in part, and implement expensive, time-consuming corrective measures—just like those Mylan was ultimately forced to implement at its Morgantown facility. Regaining the FDA's trust and remediating data integrity violations is invariably a difficult, time-consuming, and expensive process. Thus, a failure to adhere to the FDA's data integrity requirement can have serious, potentially crippling, effects on a company's ability to get its drugs approved and marketed.

56. Mylan itself acknowledged in filings with the SEC that "failure to comply with CGMP" could result in a host of serious regulatory sanctions and harm to Company's business, including "warning letter[s], fines, penalties, disgorgement, unanticipated compliance expenditures," product recalls, and even criminal prosecution.

57. Indeed, prior to and during the Class Period, several drug manufacturers experienced serious, even fatal, blows to their profitability because of their failure to adhere to CGMP and data integrity requirements, as Mylan was well aware. For instance, as discussed above, Defendant Malik served as the Head of both Pharmaceutical Development and Regulatory Affairs for Ranbaxy, whose serial violations of CGMP and data integrity standards led to the company's implosion. In 2008, the FDA issued two warning letters to Ranbaxy stemming from whistleblower reports that Ranbaxy fabricated drug test results during Defendant Malik's tenure. The FDA blocked imports from two of its manufacturing facilities as a result.

58. Likewise, in 2014, the FDA prohibited Ranbaxy from manufacturing and distributing APIs from a facility in Toansa, India, where the agency had discovered numerous CGMP and data integrity violations. Most significantly, the FDA discovered evidence that Ranbaxy was "testing into compliance"—again, successively re-testing drug products after they

failed analytical testing and inspection until passing results were achieved, without investigating, and sometimes without even reporting, the failing results.

59. As early as 1991, the FDA forced Barr Laboratories to shut down facilities in New York and New Jersey, and recalled drugs manufactured there, after issuing a Form 483 finding that the drug maker was testing into compliance. Specifically, the FDA found that the company had retested failing quality control results but had "no documentation of any meaningful investigation to determine the cause or reason" for many of the process failures observed.

60. More recently, the Delaware Court of Chancery ruled in 2018, and the Delaware Supreme Court subsequently affirmed, that Fresenius Kabi was permitted to terminate a merger agreement with generic drug maker Akorn, Inc. because the latter failed to disclose widespread CGMP and data integrity violations, including alleged instances of "testing into compliance," and failed to take reasonable steps to address the underlying violations. Significantly, the ruling represented the first time a Delaware court had ever found that a "material adverse event" clause in a merger agreement was triggered. In finding that Akorn's CGMP violations were highly material, the Chancery Court emphasized the high cost of the remedial measures necessary to cure such violations, which included halting or reducing drug production, cuts to the company's drug portfolio, replacing numerous employees in order to "build a culture of compliance," and delaying product sales.

61. Accordingly, CGMP and data integrity compliance is not only essential to consumer protection, it is highly material to investors.

D. Prior To The Class Period, Price Erosion In Mylan's Core Generics Business Placed Enormous Pressure On The Company To Sustain Morgantown's Massive Volume

62. Prior to the start of the Class Period, Mylan began to experience significant price pressures with respect to its core generics business and some of its most lucrative branded products, such as the EpiPen.

63. First, low-quality competitors were entering the marketplace and undercutting Mylan's generic drug prices and market share. Second, in 2016 and 2017, several of Mylan's large pharmacy customers began to consolidate into buying consortia with drug manufacturers. This trend placed significant pressure on Mylan to keep its prices low.

64. Analysts recognized the risks to Mylan's bottom line stemming from price erosion and consolidation among drug companies and pharmacies. As Morningstar's analyst noted in June 29, 2016, "Mylan faces considerable competition from low-cost producers, especially India-based generic drug manufacturers. Aggressive entry pricing could weaken Mylan's dominant market position." An August 9, 2017 Cantor Fitzgerald analyst report described that one of the downside risks facing Mylan was "generic drug pricing continu[ing] to decline. This could come from increasing competition for Mylan's key products. Also, customer consolidation has given buying consortiums the power to negotiate better prices, and these consortiums could continue to cause prices to fall." J.P. Morgan wrote in an August 13, 2017 analyst note that, "[W]e remain cautious on the group as elevated levels of competition and customer consolidation suggest the challenging generic pricing environment could persist for an extended period of time (i.e., through at least 2018)."

65. As discussed in more detail below, in the face of this significant pricing pressure, Mylan dramatically cut corners on CGMP compliance to maximize production and margins at its Morgantown plant.

E. Throughout The Class Period, Defendants Misled Investors About Mylan's Quality Controls and Operating Capacity

1. Defendants Assured Investors That Mylan's Quality Assurance Processes Were Robust

66. Recognizing that product quality was of the utmost importance to Mylan's business, Defendants carefully curated the Company's public image as a leader in product quality and safety. In this way, Defendants repeatedly highlighted Mylan's reputation for product quality and compliance as an important differentiator and growth driver.

67. For instance, throughout the Class Period, Mylan prominently trumpeted its manufacturing processes on the Company's website as exceeding applicable product quality standards:

- "*Quality*. Mylan applies one global quality standard across our facilities . . . . Because there's nothing generic about our standards. Our internal teams conduct reviews of all products, start to finish."
- "Mylan uses advanced testing and monitoring systems to assure product adheres to testing acceptance criteria that are in alignment with requirements established by standard-setting organizations around the world."
- "*Advanced Monitoring Systems*. Although not required, Mylan utilizes state-of-the-art monitoring systems that can automatically evaluate and reject a product that does not meet specifications. This advanced technology is used to automatically remove a defective product from production or packaging lines."
- "*One Global Quality Standard*. Whether it's a medication for millions or for a handful of people, our priorities are to meet or exceed industry standards. Our own teams conduct ongoing reviews to ensure quality and integrity of products, start to finish, and to continually improve for optimal quality and consistency."
- "*Proof of Purity and Potency*. Mylan assures product potency, purity and drug release through expiration date by testing the stability of our products at specific intervals."[3]

[3] Lead Counsel is mindful of this Court's legal writing guidance, including the Court's preference against block quotes. Throughout this Complaint, Lead Counsel has quoted certain of Defendants' allegedly false and misleading statements in full in order to provide the Court with the context of those statements. For ease of readability, Lead Counsel has formatted lengthy quotations as block quotes.

In SEC filings and at investor conferences, Mylan repeatedly encouraged investors to visit its website to understand its business.

68. Likewise, on the first day of the Class Period, Mylan filed its Annual Report with the SEC on Form 10-K, in which it highlighted Morgantown as a "significant" manufacturing facility. Mylan stated, "We believe that all of our facilities are in good operating condition, the machinery and equipment are well-maintained, the facilities are suitable for their intended purposes and they have capacities adequate for the current operations." Similarly, in the Company's May 2017 proxy statement issued to investors, Defendants stated that Mylan's key "strengths" included its "[p]owerful, high quality manufacturing platform." Specifically, Defendants stated that "[o]ur 50 plants around the world manufacture tens of billions of doses of medicine annually, and each site adheres to stringent quality standards, regardless of location."

69. Then, in April 2017, the Company received public criticisms from the FDA that threatened to undermine its reputation as a model of "stringent" quality standards. On April 3, 2017, the FDA publicly issued Mylan a warning letter citing CGMP deficiencies at the Company's Nashik, India manufacturing facility. The warning letter stated that analysts at the Nashik facility had "invalidated . . . initial failing result[s]" of quality tests "without adequate investigation, performed re-testing, and then reported the . . . results of these replicate re-tests."

70. In response, Defendants immediately downplayed the Nashik warning letter as a "one off" set of technical issues related to "evolving" FDA standards that were confined to a single foreign plant. On April 11, 2017 Mylan issued a statement claiming, "As FDA standards for our industry continue to evolve, we are dedicated to continually enhancing our systems and processes with a deliberate, thorough approach to assure sustainable quality across our entire network of facilities." Mylan also told *Investors Business Daily* that "[t]he Nashik, India, facility is just one

of Mylan's 50 manufacturing sites across the globe with 24 focused on oral solid doses. Production is ongoing and Mylan doesn't expect any supply issues related to products being manufactured at the India site."

71. Likewise, on Mylan's May 10, 2017 first quarter earnings call, Defendant Malik reassured investors about the warning letter stating that "Mylan has always had a deep and unwavering commitment to quality everywhere we operate," that Mylan was "dedicated to continually enhancing our systems and processes, with a deliberate and thorough approach to ensure sustainable quality across our entire network of facilities." Defendant Malik further stated that "[p]roduction from Nashik site continues uninterrupted, and we anticipate no material impact to Mylan's overall business as a result of this warning letter."

72. Given Mylan's carefully crafted public image as an exemplar of "stringent" product quality standards, investors credited Defendants' soothing statements. For instance, in a May 10, 2017 report, BMO analysts reported that the issues identified were well on their way to remediation. Likewise, Susquehanna analysts issued a May 11, 2017 report crediting Mylan's "affirm[ation] that it doesn't expect a material impact from the warning letter on the Nashik, Indian manufacturing plant."

73. Unbeknownst to investors, these same CGMP failures were widespread throughout Mylan's facilities, including its critical Morgantown plant—the cornerstone of its U.S. operations. In fact, Mylan had already received the thorough and scathing 2016 Form 483 concerning the Morgantown facility. However, Defendant Malik failed to disclose the 2016 Form 483, the financial and regulatory risk it entailed, or the costly measures the Company would have to implement to address the violations the FDA discovered.

74. Instead, Defendants held the Morgantown facility up to the market as an exemplar of the Company's rigorous quality control standards. For instance, in October 2017, Defendant Bresch led a tour of the facility for journalists specifically to emphasize Morgantown's purportedly high-quality standards. As West Virginia's *State Journal* reported on October 23, 2017, Defendant Bresch told reporters that "[q]uality is not a department here"—instead, it was Mylan's whole corporate philosophy. Specifically, based on Defendant Bresch's statements during the tour, the article reported:

> Bresch said Mylan prides itself on cleanliness and quality control. "Quality is not a department here," she said from the company board room following a tour of the plant. For Mylan, quality control is a corporate philosophy. And it begins before the first chemical is mixed. Technicians hand-wash each and every barrel of raw material before it goes into Mylan's warehouse. Containers of ingredients for making pills are transferred from wooden pallets to plastic skids, which are also painstakingly cleaned. Samples of each ingredient are tested to make certain they are what they are said to be. Similar testing goes on during all aspects of tablet and capsule production.

75. Throughout the remainder of the Class Period, Defendants continued to assure investors that Mylan adhered to the highest manufacturing standards and touted the Company's robust quality controls. For instance, in an annual governance report issued to shareholders in June 2017, Mylan told the market that it had "invested significant resources to ensure quality throughout our value chain. Each of its steps is wrapped in a series of reviews designed to meet or exceed the many regulatory and compliance standards enforced by the dozens of health authorities around the globe that regularly inspect us."

76. And in the Company's May 2018 governance report, Defendants continued to tout Mylan's rigorous quality control processes and "extensive, formal internal-audit program." In that report, Defendants stated, for instance, "Mylan has global systems and processes in place to provide our people with the foundation and tools needed to maintain an effective quality management system . . . . Our Quality Council program provides management with clear,

quantitative data, including that of key performance indicators. It also tracks and analyzes quality trends, reviews inspection results and identifies potential areas for employee training."

77. As discussed below, Defendants failed to disclose that, among other things, by April 2018 the FDA had again concluded that Mylan's Quality Council had failed to appropriately apply and enforce CGMP and data integrity standards at the Morgantown facility.

78. Analysts credited these claims. For example, throughout the Class Period, Susquehanna consistently noted Mylan's "global quality standard" as a key characteristic of the Company. Similarly, BTIG described in an October 9, 2016 report Mylan's "Critical Mass with High Quality Manufacturing Capabilities Globally," observing that, "[o]ver the years, Mylan has built a strong reputation as a quality drug manufacturer."

2. Defendants Touted Mylan's "Broad" Operating Capacity And Assured Investors That The Company Did Not Need To Downsize Its Generics Portfolio

79. Throughout the Class Period, Defendants also made materially false and misleading statements touting the Company's "broad" operating capacity, specifically its ability to manufacture a huge volume of a broad range of drugs. In addition, Defendants assured the market that the Company did not need to downsize its generics portfolio, even as Defendants knew that its flagship Morgantown facility would have to dramatically reduce its output in order to meet its regulatory obligations. And, as set forth above, Mylan told investors that it was "able to manufacture tens of billions of doses of medicine annually, all to stringent quality standards."

80. These statements were a key selling point for the Company. For example, at the June 2016 Goldman Sachs Healthcare Conference, Defendant Bresch told investors that Mylan's operating capacity gave the Company a significant competitive advantage in attracting and retaining customers: "It's always been a volume-driven business, always . . . . [T]here's a much—more of a sense from our customer base that having a reliable global supply chain is important,

that they don't want to have to turn customers away because of products—they're not able to get their hands on a product." Similarly, at a January 2018 J.P. Morgan Healthcare Conference, Defendant Bresch claimed that "where Mylan has differentiated itself is, one, having that broad base, that portfolio, the capacity to truly meet the supply that's needed . . . . And all of that gives us a seat at the table perhaps a bit differently than our peers."

81. Defendants also stated that the Company's vast operating capacity not only allowed it to negotiate favorable prices with its customers, but also to quickly enter markets affected by shortages and capture favorable pricing. Further, Defendants repeatedly denied that Mylan needed to cede this advantage and "rationalize" its portfolio. For example, at the January 2018 J.P. Morgan investor conference discussed above, an analyst asked whether Mylan needed to reduce its generics portfolio in order to limit its exposure to "loss-making products." Defendant Bresch, specifically referencing the Morgantown facility touted the fact that Mylan was "running facilities that are making 15 billion tablets and capsules in a year." Defendant Bresch explained that "you could be making less money on one day, you could be making more on the next, given the dynamics in the supply chain. So, for us, as others are having financial constraints or having to make perhaps short-term decisions because they have to, I think we have found ourselves in a position to really take into consideration again that long-term view." At that same conference, Defendant Bresch later emphasized this point: "[A]s other companies are forced to rationalize [Mylan is] able to absorb those different volumes is what we've really been set up to do."

F. In Truth, Mylan's Manufacturing Facilities, Including Its Key Morgantown Plant, Were Rife With Serious CGMP And Data Integrity Failures

82. In truth, and unbeknownst to investors, Mylan's manufacturing facilities, including its flagship Morgantown facility, were rife with systemic, egregious, and long-standing CGMP and data integrity failures. These failures exposed the Company to serious regulatory penalties, costly

disruptions, and expensive remediation. Far from "conduct[ing] reviews of all products, start to finish" and "us[ing] advanced testing and monitoring systems to assure product adheres to testing acceptance criteria," Mylan failed to perform quality assurance testing on the vast majority of the products manufactured at Morgantown. When testing did occur, Mylan routinely engaged in improper "testing into compliance" by repeatedly re-testing drug products after they failed inspection until passing results were achieved without investigating the failing results. Mylan systematically misstated investigative findings, altered drug samples, "improperly invalidated" reports of defects, and engaged in suspect data practices designed to avoid recording failing quality testing results on internal systems, including by crashing them.

83. Moreover, contrary to Defendants' statements touting Mylan's "broad" operating capacity and assuring investors that the Company did not need to "rationalize" its generics portfolio, Defendants knew, and admitted in private correspondence with the FDA, that "the large volume of doses and products within the Morgantown portfolio . . . inhibited [Mylan's] ability to achieve the high level of control over our manufacturing processes that we expect." As former Mylan employees explained, and as the Company itself acknowledged, Mylan failed to perform the rigorous quality testing it assured investors it was performing on "all products, start to finish" because the Company's single-minded focus on production volume made doing so impossible. Accordingly, Mylan was ultimately forced to halt production at Morgantown and reduce the facility's generics portfolio by nearly two thirds.

84. As discussed further below, Defendants received numerous warnings of Mylan's widespread and serious CGMP and data integrity failures, including scathing non-public reports directly from the FDA detailing these practices at several Mylan facilities, including Morgantown. Mylan also participated in private meetings with the agency to discuss these findings and was

forced to recall numerous products tied to Morgantown. Yet, astonishingly, Defendants still failed to address Mylan's profound consumer safety failures and the gaping holes in its CGMP compliance, even as they touted the Company's quality assurance processes and operating platform to investors.

2. Prior To The Start Of The Class Period, Defendants Received Numerous Warnings Of CGMP And Data Integrity Failures At Mylan, Including At Morgantown

85. As *Bottle of Lies* later revealed in 2019, a Mylan whistleblower traveled to the FDA's Maryland headquarters in mid-2015 and reported that "under Rajiv Malik's leadership," Mylan's research and development center in Hyderabad "had become a hub for data fraud that had disseminated its methods of falsification throughout Mylan's Indian operations." The whistleblower further reported that the masterminds of the data fraud techniques "held key leadership positions at Mylan" and included former Ranbaxy employees. As *Bloomberg* reported in January 2019, the whistleblower raised concerns about CGMP and data integrity violations at Morgantown, reporting "unscrupulous activity at the factory where the generic giant makes some of its top-selling drugs."

86. Among other things, the whistleblower reported that in order to generate passing product quality testing results, commercial samples of specific drugs bound for the U.S. market had been switched with more stable pilot samples. In addition, the whistleblower reported that Mylan was not only "testing into compliance," but it also had developed a novel method for hiding the fact that the Company was repeatedly re-testing failing samples until passing results were obtained. Instead of deleting or altering failing test results, which would have left a trail of metadata for FDA investigators, plant managers deliberately corrupted data files and crashed computers when the instruments used for quality analysis began to indicate that an out-of-

specification ("OOS") result was inevitable. According to the whistleblower, Defendant Malik's team had instructed Mylan personnel that this was a better way to evade investigators.

87. Former Mylan employees echoed the FDA whistleblower's report. For instance, *Bottle of Lies* recounts an interview with a former Mylan chemist who described how Mylan had moved dozens of generic drug applications swiftly through the system, using "cooked" data at each step of the manufacturing process. According to the Mylan chemist, this manipulation occurred under the leadership of Defendant Malik and his team. The Mylan chemist stated that Defendant Malik's team used an array of deceptive methods to hasten approval of critical products. For instance, the chemist reported that Mylan generated bioequivalence data by switching drug samples, using hidden equipment to tinker with secret substitutions.

88. Defendant Malik also deployed research and development teams to different sites to manage failing data. The Mylan chemist reported that when commercial drug batches, like those manufactured at Morgantown, failed on stability, "[y]ou play with the parameters so impurities don't show up." At each step, "people come from [research and development] to show how to fix the issue." Based on his objections to the data manipulation he witnessed, the Mylan chemist resigned and, shortly thereafter, "detailed his allegations in writing to senior managers."

89. FDA memoranda (which Katherine Eban reviewed) demonstrate that the agency found the whistleblower's claims credible. However, the agency was apparently reluctant to strike at the heart of Mylan's operations.

90. In 2016, the whistleblower privately sent the FDA a follow-up email that jolted the agency out of inaction. The whistleblower warned the FDA that its inaction could harm American patients: "Perhaps the agency awaits a definitive tragedy to occur on U.S. soil due to substandard generic drug products not meeting the safety & efficacy standards." The whistleblower continued,

"Honestly—I had supreme faith & trust in the agency's approach—towards bringing those to justice who commit fraud."

3. The Nashik Form 483

91. As Eban reported, the whistleblower's admonishment set off a scramble inside the FDA. Approximately two months later, on September 5, 2016, the FDA arrived at Mylan's Nashik, India facility to conduct a surprise inspection. Throughout their nine-day inspection of the Nashik plant, FDA investigators found evidence strongly corroborating the whistleblower's report. As a result, the FDA privately issued a lengthy Form 483 to the Company (the "Nashik Form 483").

92. The Nashik Form 483 shows that, as the whistleblower reported, failing or OOS results "were invalidated without sound scientific justification." Instead, Mylan either conducted no investigation into the cause of the failures or invalidated them for clearly pretextual reasons.

93. Indeed, investigators found that the plant's software had recorded scores of error messages showing "instrument malfunction," "power loss," and "connection to chromatography system lost." Significantly, plant managers had apparently conducted no investigation into the repeated crashes. Instead, Mylan re-tested the drugs after receiving the error messages, indicating that computers had been suddenly shut down in the midst of analyses in order to avoid recording failing results and facilitate re-testing—i.e., "test into compliance"—just as the whistleblower had reported. This technique was so notable that the FDA gave it a nickname: "crashing files."

94. The FDA investigators also found that "[e]quipment and utensils are not cleaned and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product."

4. The FDA's Surprise Inspection Of Morgantown In 2016

95. Less than two months later, on November 7, 2016, and unbeknownst to investors, three international FDA investigators, including the investigator who had conducted the Nashik

inspection, arrived unannounced at Mylan's Morgantown facility. FE1[4] worked at Morgantown for years prior to the start of the Class Period until May 2017 and held positions in Quality Control and as a Technical Area Lead in Packaging during the Class Period. As he reported, a surprise FDA inspection of Morgantown was highly unusual. Typically, Mylan scheduled inspections of Morgantown in advance, agreeing with inspectors from the local FDA office on a mutually convenient date.

96. As Eban reported in 2019, the international FDA investigators who visited Morgantown in November 2016 were "stunned" to discover a host of egregious violations of core CGMP and data integrity regulations, including testing into compliance and other "suspect data practices." Indeed, the volume and severity of Mylan's improper practices forced the FDA to add a fourth international inspector to join the team.

97. Unbeknownst to investors, on November 18, 2016, following the surprise inspection, the FDA privately issued a lengthy Form 483 addressed to Mylan's Head of Global Quality Operations, Reem Malki. In the 2016 Form 483, investigators reported that they observed numerous instances of "testing into compliance" involving several different drugs, including drugs Mylan would later be forced to recall.

98. Specifically, the 2016 Form 483 stated that while testing of these drug batches had yielded "out-of-specification ('OOS'), out-of-trend ('OOT') and other anomalous results, [they] were retested without any investigation" into the causes of the failing or anomalous results until passing results were obtained and were then "released" to the American public. As discussed

[4] The terms "Former Employees" and "FE" refer to the former Mylan employees whose reports are discussed in this Complaint. In order to preserve the Former Employees' anonymity while maintaining readability, the Complaint uses the pronouns "he" and "his" in connection with all the Former Employees, regardless of actual gender.

above, successive retesting of failing quality and safety results, without conducting a CGMP-mandated investigation into the cause of the failure, strongly indicates the batches, equipment, or analyses were manipulated simply to achieve passing results and to avoid costly production delays or product recalls. Moreover, Mylan's practice of testing into compliance was directly contrary to Defendants' public statements, including that the Company "conduct[ed] reviews of all products, start to finish" and "uses advanced testing and monitoring systems to assure product adheres to testing acceptance criteria."

99. In other cases, investigators discovered that failing test results had been invalidated for apparently pretextual reasons. Once again, tests were then re-run until Mylan obtained passing results. For instance, the 2016 Form 483 noted that several Mylan Trending Assessment reports showed that failing test results were chronically attributed to dirty glassware. "This attribution of OOS results to glassware contamination has been a continued practice at your firm with no effective resolution, and is utilized to invalidate failing results." Accordingly, investigators' findings made clear that one of two things was occurring: either the flagship plant of one the most experienced and sophisticated drug manufacturers in the world was suddenly struggling to clean its glassware and was doing little to address the problem, or Mylan was not being truthful about the reasons it was invalidating failing results.

100. Indeed, the FDA observed that, in some cases, the analysts either did not report the initial failure at all, or misreported the data relating to it. The FDA also pointed out that despite "the mishandling of analytical data by these analysts," Mylan's Director of Analytical Investigations acknowledged that "no assessment of the analyst's previous and other work had been conducted." Mylan's failure to assess the analyst's previous work contravened data integrity standards.

101. Likewise, FDA investigators discovered that technicians had been pre-injecting drug samples into gas chromatographs "prior to official analyses," apparently to preview the test results and avoid recording an official failure. While Mylan executives on the Company's Quality Unit later told FDA investigators that the injections were done for purposes of instrument setup, the FDA noted that the data did not appear to support that explanation. First, the names assigned to these analyses in Mylan's systems appeared either designed to obscure their purpose or confirmed that they were trial or test injections, including names like "TEST," "Besylate ID," "lop," "0," and "New MP test injects LMFAO"—a popular acronym for "laughing my f--- a-- off," suggesting the analyst was "laughing" at the notion that the injections were "new." Second, the FDA pointed out that the "area values"—the output—of the suspect analyses "are similar to standards and samples run during the official analyses," indicating that analysts were actually attempting to preview test results for batch samples, not setting up their instruments.

102. Moreover, and consistent with the conclusion that Mylan was "testing into compliance," the FDA also found that Mylan had significantly altered drug sample sets—including changes to sample weight, composite weight, and dilution factor—and no investigation had been conducted to determine whether changes were made for valid reasons. Notably, the FDA found that this improper practice had occurred in connection with valsartan, a drug that Mylan would later recall because it had been contaminated with known carcinogens.

103. Also consistent with these suspect data practices, the FDA found bins full of shredded data and quality control records in Morgantown's Quality Control, Quality Assurance, and Packaging areas—areas where, pursuant to CGMP requirements, every piece of paper is supposed to be saved.

104. In addition, the FDA found that Mylan failed to contemporaneously validate that the test methods supposedly used to certify drug products, including APIs, met specification. The FDA cited numerous instances in which validation of stability testing occurred months or even years after quality testing was supposedly performed.

105. The FDA further pointed out that Mylan "manufacture[d] drug products despite an awareness of manufacturing investigation reports and complaints related to known repeated manufacturing deficiencies," including by "inappropriately" invalidating consumer complaints.

106. Accordingly, the FDA concluded, among other things, that Mylan's Morgantown plant failed to meet core CGMP and data integrity requirements. The FDA concluded that Mylan's "[l]aboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity," as required by 21 C.F.R. § 211.160; and "[t]here is a failure to thoroughly review any unexplained discrepancy [between quality test results and required product standards] whether or not the batch has already been distributed," as required by 21 C.F.R. § 211.192. The FDA classified the Morgantown inspection as "Official Action Indicated," the most serious classification in the agency's inspection rating system, which, the FDA explains, "means regulatory and/or administrative actions will be recommended." In other words, Mylan was warned that the violations were of the utmost seriousness and that investigators would recommend the Company receive additional regulatory sanctions.

107. The FDA did not publicly disclose the 2016 Form 483. Defendants continued to issue misstatements touting Mylan's supposed adherence to strict quality control measures and its rigorous and robust quality assurance processes.

5. Mylan Former Employees Corroborate The FDA's Findings

108. Former Mylan quality personnel confirmed the FDA's findings of egregious and systemic CGMP and data integrity violations at Morgantown and other Mylan facilities. Just as the FDA privately warned Mylan in its 2016 Form 483, Former Employees have confirmed that these violations were widespread throughout Morgantown long before the FDA's November 2016 inspection and were known to senior management.

109. First, Mylan's former employees confirmed that "testing into compliance" was a bedrock practice at Morgantown from before the Class Period and throughout—continuing even after the 2016 Form 283 was issued, as the FDA later confirmed. For example, as discussed above, FE1 worked at Morgantown for years prior to the start of the Class Period until May 2017 and held positions in Quality Control and as a Technical Area Lead in Packaging during the Class Period. FE1 echoed the FDA's findings that the practice of retesting OOS drug products and equipment until passing results were obtained was widespread at Morgantown for years prior to the start of the Class Period and throughout the remainder of his tenure at the Company. FE1 stated, "the FDA calls that 'testing into compliance.'" FE1 stated, Mylan "never looked into why we are having failures and how can we avoid them in the future . . . instead of investigating, they said we need to get this batch out." FE1 explained that batches with failing results should be flagged and held until an appropriate root cause analysis determines the reason for failure, "but I can't ever remember doing that at Mylan."

110. FE1 also reported these issues to senior Mylan executives. FE1 flagged both (i) Morgantown's failure to test the vast majority of its manufactured drugs and equipment (discussed below) and (ii) its widespread "testing into compliance" to senior Mylan executives, including Kim Kupec, Head of Quality at Morgantown, and Eddie Koski, Senior Director of Quality

Assurance Operations, in meetings in 2015 and 2016, prior to the FDA's issuance of the Form 483, but his concerns were ignored.

111. FE2, a Quality Assurance Specialist at Morgantown from prior to the start of the Class Period until April 2018, likewise reported that Mylan "100%" tested into compliance at Morgantown and, indeed, the practice was widespread throughout his tenure at Mylan. FE2, who was responsible for analyzing drugs and equipment for compliance with quality standards, stated that at the express direction of Quality Assurance supervisors, he and other technicians would re-test samples yielding OOS or anomalous results until they passed, without any investigation into the failing results. FE2 stated that Quality Assurance supervisors instructed technicians to "just run it until it passes." FE2 stated that "testing into compliance," as directed by Quality Assurance supervisors, continued unabated throughout his tenure at Morgantown.

112. FE3, a chemist responsible for quality control and validation at Morgantown from 2016 to 2019, similarly confirmed that throughout his tenure until at least the FDA issued its 2018 Form 483 (discussed below), failing results were routinely retested until passing results were obtained without any investigation or root cause analysis. Indeed, FE3 reported that Morgantown analysts would "test into compliance" using serial retesting to artificially shift entire trends. As FE3 explained, "If you take something that's out of trend and test it enough, that becomes the trend." Moreover, FE3 echoed the FDA's findings, stating that analysts cited "dirty glassware" or "analyst error" as stock justifications for invalidating results where the cause of the failure could not otherwise be identified.

113. Likewise, FE4, a quality control chemist at Morgantown from prior to the start of the Class Period until mid-2016, reported that "testing into compliance"—which he described as repeating testing until you "miraculously" get the results you need to pass—was "commonplace"

at the facility throughout his tenure. According to FE4, Morgantown personnel lacked the time and resources to meaningfully investigate failing quality tests because Morgantown's volume was so overwhelming.

114. FE4 reported that, in his experience, "testing into compliance" occurred most frequently in connection with product "stability testing," which determines whether a product maintains its strength, purity, and integrity throughout its shelf life. A failing result would have to be promptly reported to the FDA and would trigger a recall. FE4 reported that when test results exceeded the threshold for a recall, they would be rerun multiple times, until the analysts obtained a result just under the recall threshold. All the preceding failing results would then be attributed to stock justifications, most commonly, "analyst error" or "dirty glassware." Importantly, quality assurance management instructed analysts that when the raw data showed results exceeding the recall threshold, those data should not be "processed" because doing so would start the "clock running" for notifying the FDA. Instead, the analysts were told to meet with quality managers in order to come up with a "game plan" for re-testing the drugs.

115. FE5, a Quality Compliance Manager from prior to the start of the Class Period to November 2016, also reported that failing results were re-tested without adequate investigation at numerous Mylan sites, including Morgantown, Nashik, and Bangalore, throughout his tenure at Mylan. Among other things, FE5 echoed that Morgantown personnel improperly used boilerplate justifications for invalidating failing results. The Company's failure to develop corrective and preventative actions in response to the trend of such events demonstrated that the justifications were pretextual.

116. Second, Mylan's former employees further echoed the FDA's findings concerning a host of additional suspect data practices and reported that they were in use well before the FDA

discovered them during the November 2016 inspection. For instance, the Former Employees reported that, as the FDA concluded in 2016, the Morgantown facility consistently "pre-injected" drug samples to avoid recording bad results. FE1 stated that, prior to the 2016 Form 483, it was a widespread practice at Morgantown to improperly re-inject drug samples into gas chromatographs prior to official analyses. After the issuance of the 2016 Form 483, Mylan continued the practice, but "it became more covert." FE1 stated that analysts "would inject chromatograph and if it came out wrong, out of spec or whatever, it was common practice to just rerun the test."

117. FE4 also reported that, during his tenure, Morgantown personnel pre-injected samples in connection with a variety of different tests, including stability and production testing, to "see where the numbers were."

118. Similarly, Mylan's former employees confirmed the FDA's findings that the Morgantown facility engaged in the improper practice that the FDA dubbed "crashing files." FE1 stated that when computers showed analyses were failing, power to the instruments was cut or the computers were crashed to avoid recording a failing result. For instance, FE1 explained that Morgantown's tablet presses had computers that would monitor tablets to ensure they met specifications. If tablets were out of specification, an alert would trigger a "red screen" on the machine's monitor. CGMP standards required Mylan to open an investigation when this occurred but doing so would-be time consuming and would halt production for up to an hour. To avoid this, employees would shut down the machine. Once rebooted, the OOS result would not be recorded; the instrument would only log "down time" or "loss of power." FE2 likewise reported that he and other technicians received instructions from Quality Assurance supervisors to abort analyses, e.g., dissolution tests, when testing indicated an OOS result was imminent.

119. Notably, Defendants had previously been warned that the practice of "crashing files" was widespread at Morgantown. As described above, in 2009, Mylan sued the *Pittsburgh Post-Gazette* after the newspaper reported that, at Morgantown, plant employees regularly "crashed files" (among other unscrupulous tactics) to evade FDA regulations. In response, Mylan not only vigorously and falsely denied the newspaper's allegations, but also sued the *Post-Gazette* for misappropriation of trade secrets and libel. In its complaint, Mylan claimed that the newspaper's reporting would "adversely affect" its business reputation; "impugn the integrity" of its procedures and personnel; and "threaten [its] current and prospective business relationships." The Company further asserted that the publicization of the *Post-Gazette's* allegations "caused harm to Mylan and its shareholders, evidenced by substantial market volatility, a decrease in its stock price, and the resulting decrease in market capitalization."

120. Third, Mylan's former employees confirmed that Morgantown analysts manipulated test reports. FE1 reported that Morgantown analysts routinely failed to record results and observations contemporaneously, altered reported results to meet specifications, and certified analyses had been performed when they had not. As an example, FE1 explained, if "you get 10.1 and your spec is not supposed to be above 10, I saw people scratch out the .1 and add two 0's so you get 10.00." Former Employees also reported being asked to falsify evidence of CGMP remediation. For instance, FE5 traveled to Bangalore to prepare for an upcoming FDA inspection. Mylan's Associate Director of Global Compliance instructed him to falsely certify that certain training had been completed, that certain operational guidelines had been issued, and that other CGMP failures had been addressed.

121. Fourth, directly contrary to Defendants' statements that Mylan "conduct[ed] reviews of all products, start to finish," Mylan in fact quality tested only a tiny fraction of the drugs

manufactured at the Morgantown facility. FE1 reported that, beginning in the late 2000's and through the remainder of his tenure, Mylan performed product quality testing on no more than 5% of the drugs manufactured at Morgantown because production demands made broader testing impossible. Notably, FE1 reported that before Morgantown dramatically scaled back its testing in the late 2000's, shortly after Defendant Malik's arrival at the Company, Mylan had performed quality testing on every drug manufactured at the facility.

122. Corroborating FE1's report, FE3 stated that only 3% to 5% of the drugs manufactured at Morgantown were actually subject to product quality testing during his tenure because the enormous production volume flowing through the facility made more comprehensive testing impossible. According to FE3, Morgantown's testing covered a "shockingly low percentage" of the drug manufactured at the facility. He explained, "I would see the numbers and think 'If we're failing at this [low testing rate], what does that mean for other products?'"

123. Notably, in a private May 2018 letter to the FDA, Mylan acknowledged that it previously failed to perform "quality risk assessments" on "all products manufactured at Morgantown."

124. FE1 likewise reported that quality testing of the equipment used to manufacture drugs was extremely limited for years prior to the start of the Class Period and throughout the remainder of his tenure. In many cases, that equipment was swabbed no more than once a year, and, predictably, the equipment would pass only after repeated retesting, while, again, analysts failed to investigate the failing results. "A lot of times we'd swab one piece of equipment one time in a year. Then at end of the year, you would say [to analysts and manufacturing personnel] you only did it once, but they'd say, that's okay, it passed. But it only passed because it passed the fourth time after failing three times."

125. Even with the facility's minimal testing, FE1 reported that as of July 2016, a few months prior to the FDA's 2016 inspection, Morgantown had a three-month backlog of open and unresolved investigations for product quality failures, which he was responsible for helping to close out. Mylan was thus not only failing to test the vast majority of its drugs for adulteration, it was also failing to timely investigate and resolve known quality deficiencies, just as the FDA's investigation made clear. FE1 explained that the Company's failure to timely resolve these investigations violated Mylan's own operating procedures, which required the Company to resolve investigations within 30 days or, in some cases, 45 days. FE1 reported that the backlog of open investigations was logged into the Company's incident report tracking system, called TrackWise.

126. Fifth, FE1 echoed the FDA's findings that the senior leadership of Mylan's Quality function failed to perform oversight duties mandated by Mylan's operating procedures. For instance, as the 2016 Form 483 explains, Mylan's operating procedures tasked Morgantown's Trending Review Board, comprised of "site senior leadership," including the directors of the different departments, with evaluating and remediating repeat quality failures. FE1 reported, however, that in 2016, the Trending Review Board simply stopped performing its function. As discussed above and below, FDA investigators arrived at the same conclusion.

127. Sixth, FE1 further reported numerous instances of cross-contamination at Morgantown, in which drugs were contaminated with residue from drugs previously manufactured on the same equipment. In some instances, drug batches contained whole or broken tablets of foreign drugs. These cross-contamination events were logged into the Company's incident report tracking system, called TrackWise, and the data showed a significant trend of these events. According to FE1, these cross-contamination issues represented serious CGMP violations. Employees repeatedly raised these issues with senior Quality personnel, but the senior personnel

failed to implement any meaningful remedial measures. Instead, management implemented "band-aid" fixes, such as patching holes and crevices in equipment in an ad-hoc fashion.

128. FE3 also reported that the numerous cleaning validation CGMP violations identified by the FDA in both 2016 and later in 2018, including high swab failure rates for cross-contamination risk, persisted throughout his tenure until at least after the FDA's 2018 Form 483. FE3 stated that because Mylan failed to test the vast majority of the drug products manufactured at Morgantown, numerous rooms within the facility were visibly cross-contaminated, as the FDA observed in both 2016 and 2018. FE3 stated that this was "a huge product and consumer safety issue," as the FDA pointed out, because drugs manufactured in those rooms could contain traces of other drugs or foreign material to which a patient might react adversely. In fact, as discussed above, the FDA cited numerous examples of cross-contaminated drugs manufactured at Morgantown. Moreover, FE3 confirmed the FDA's findings that failing results showing cross-contamination risk were invalidated and retested if a re-swab in another location of the equipment yielded passing results, and that this practice occurred throughout his tenure at Morgantown at least until April 2018. In other instances, failing swab results were invalidated without any re-testing. Indeed, FE3 reported that analysts were discouraged from thoroughly swabbing rooms because any "extra" swabs could turn up evidence of contamination and yield failing results, triggering a time-consuming investigation.

129. Mylan senior management was well aware of these egregious violations of FDA regulations. FE1 corroborated reports from both the 2015 FDA whistleblower and the Mylan chemist that Defendant Malik's team visited Mylan's plants, including Morgantown, to coach personnel on data fraud techniques, particularly when new products were being scaled up for commercialization. For instance, FE1 explained that when Morgantown first started making

divalproex (prior to the start of the Class Period), a seizure treatment, the FDA asked Mylan to make 100 batches and send it to the agency for testing. Defendant Malik's team came to the facility to oversee the process and, when batches failed quality testing, they instructed employees to destroy the batch and create a replacement, thus concealing the product failure from the FDA.

6. The Morgantown Facility's Enormous Volume Drove Mylan's Violations Of CGMP Standards

130. Mylan's Former Employees reported that Morgantown's severe CGMP and data integrity issues were a direct result of the unrealistic production demands Mylan's leadership placed on the facility. These production demands strained the site's manufacturing capacity past its breaking point and made compliance with the most fundamental product quality requirements impossible. While Mylan eventually admitted that its exclusive focus on volume had undermined compliance with CGMP regulations, Former Employees report that this overwhelming strain was known internally at Mylan throughout the Class Period.

131. For example, FE6 was a Lead Financial Analyst at Mylan from prior to the Class Period to spring 2018. FE6 was assigned to Morgantown and helped oversee the site operations budget, with significant work on the Company's quality budget. Among others, FE6 supported the Vice President and Site Head of Quality at Morgantown. FE6 reported that even prior to the start of the Class Period, senior Mylan executives knew and routinely discussed that it was impossible for Morgantown to both meet the facility's outsized production demands and satisfy its CGMP compliance and product quality obligations.

132. In particular, FE6 explained that Morgantown's yearly budget, which set the number of doses Morgantown was expected to produce, put enormous pressure on the facility to meet extraordinary production goals. FE6 stated that the budget was approved by Defendant Malik and Mylan's Global Chief Operating Officer, Dr. Hari Babu. If Morgantown leadership proposed

a production target that Defendant Malik felt was not ambitious enough, he would say so. FE6 reported that in 2012, Morgantown produced more than 21 billion doses. Yet, FE6 explained, as Morgantown began to produce more complex medicines, the facility's regulatory compliance and quality requirements also became more complex and time-consuming. As an example, FE6 explained that equipment now needed to be broken down, cleaned, and inspected more frequently. However, FE6 explained that Morgantown's production targets failed to account for this, and continued to budget unrealistic production volumes that, year after year, the facility failed to meet. FE6 stated that Morgantown's budget failed to account for the fact that "changing the product we were producing in the plant was going to change our capability to meet" management's production targets.

133. FE6 reported that these issues were frequently discussed at weekly Morgantown production meetings he attended throughout 2014 and 2015, along with Mylan's Vice President of Operations, the Head of the Morgantown facility, and the Heads of Quality and Manufacturing at Morgantown, respectively, among other senior executives. FE6 stated that the "consistent drumbeat" at these meetings was that, given the resources available to Morgantown and the complexity of the products, it was impossible to meet both the facility's production demands and its product quality responsibilities. FE6 stated that the supervisors who attended these meetings consistently reported that "there was not enough time in the day" to break down and clean equipment properly before moving on to the next product. Likewise, FE6 reported that the executives in attendance at these meetings frequently discussed the enormous backlog of unresolved investigations into failing quality testing results: it was "always about the backlog."

134. FE6 reported that, as he discussed with the facility's Head of Quality, Morgantown's CGMP compliance went "downhill" as a result of its efforts to meet management's production goals, and the facility began to receive negative observations from the FDA.

135. FE6 reported that despite the strain on Morgantown's operating capacity, Defendant Malik insisted on cuts to Morgantown's quality budget every year. FE6 reported that these cuts were not informed by Morgantown's quality compliance needs. Instead, Defendant Malik would simply order Morgantown personnel to cut an arbitrary amount from the budget or lay off an arbitrary number of employees.

136. Likewise, as discussed above, FE1 reported that, for years prior to the start of the Class Period and throughout the remainder of his tenure at the Company, Morgantown's severe CGMP and data integrity issues, including widespread "testing into compliance," were a direct result of the enormous volume of drugs Mylan pushed through the facility. Likewise, FE1 explained that the enormous backlog of unresolved investigations was a function of the overwhelming pace and scope of production at Morgantown. According to FE1, it was not feasible to adequately investigate all of the quality failures observed at the facility without crippling production. Moreover, as discussed above, FE1 reported that Mylan performed product quality testing on no more than 5% of the drugs manufactured at Morgantown because production demands made broader testing impossible.

137. Similarly, FE2 reported that Morgantown's CGMP failures, including its widespread practice of "testing into compliance," was driven by the facility's overwhelming production volume. FE2 reported, for instance, that Quality Assurance was understaffed throughout his tenure and because of the speed at which Mylan insisted product be produced, a single technician was often responsible for inspection and analysis of 12 or more manufacturing

"rooms" during a single shift—far too many to allow for a thorough investigation of defects and anomalies, or compliance with other CGMP requirements.

138. Likewise, FE2 stated that while two or more quality assurance technicians were required to perform certain tasks in "high potency" manufacturing rooms (rooms in which fentanyl and other dangerous products were made), supervisors instructed FE2 and others to perform those tasks alone in order to keep up with the facility's volume. In addition, if defects or anomalies were reported in these sensitive rooms, supervisors would complain that tasks were not being completed quickly enough and the issues would receive only a "band-aid" fix to keep production moving. In another example (similar to examples ultimately cited in the FDA's 2018 Form 483, discussed below), FE2 reported discoloration of levothyroxine tablets indicating cross-contamination, but Mylan's Quality Assurance Operations Manager instructed FE2 to push the defective tablets through. FE2 further reported that technicians were encouraged to refrain from swabbing rooms and equipment to check for foreign drug residue—a critical step in preventing cross-contamination—in order to avoid production delays.

139. Similarly, FE4, stated that Morgantown's "astronomical" production volume "was not a cause, it was the cause" of the facility's CGMP failures, including pervasive "testing into compliance." Morgantown simply did not have the resources to comply with its regulatory obligations given the extraordinary volume of product Mylan's senior management attempted to push through the facility.

140. FE4 explained that Mylan would sell product before it was manufactured. Thus, there was tremendous pressure to push volume through Morgantown in order to meet the Company's sizeable commitments. Quality Control was perceived as the "bottleneck" stopping drugs from getting out the door. There were only about 100 people in the quality department

testing materials being made and sold by over 4,000 manufacturing and salespeople. FE4 stated that employees were "always under high pressure" and "always behind" in the lab. Analysts were expected to do all their testing in one day, generate data overnight, and come in the next day and test something new. This left almost no time for something to go wrong. FE4 reported that investigations of failing or anomalous results could only take place if they could be "squeezed in." And, as discussed above, when investigations were conducted, they were not meaningful. Failing analyses would often be passed off to someone else for re-testing, who would then come back to the original analyst, perhaps a month later, and ask them to sign off on analyses showing passing results and to state that the initial failing results were the product of analyst error. FE4 stated, "How am I supposed to [affirm that] I pipetted wrong a month ago?"

141. According to FE4, trying to do all the required testing under one roof was "insane." No other facility in the world, including China or India, pushed out as many different products at that much volume. FE4 stated that "there was no way" Mylan's leadership, including its senior Quality executives, could have failed to know that the volume was "insane" and adequate investigation was impossible. Anyone with a background in this industry would have understood the resources required to adequately investigate and test the products given the volume.

142. In addition, according to FE4, there was so much volume that there was not enough equipment to go around, and certainly not enough time to clean and prepare it appropriately. The maintenance was "so bad" that the Company wanted analysts to get trained to fix their own instruments because the department in charge of it could not keep up.

143. FE7 was a Quality Assurance Supervisor from prior to the Class Period until November 2018 and was responsible for supervising technicians who conducted quality assurance testing at Morgantown. He likewise reported that it was "almost impossible" to comply with the

FDA's quality requirements because the facility was "going full barrel" and "producing a ton of product." Indeed, FE7 reported that at three meetings between the end of 2015 and November 2016—even before the FDA issued the 2016 Form 483 to Morgantown—John Sylvester, Head of OSD Site Operations at Morgantown, stated that the volume and pace of production was causing, and would continue to cause, significant CGMP compliance problems, particularly around cleaning and contamination. FE7 stated that Sylvester was concerned that these CGMP issues were accelerating because customers were demanding smaller lots of products, which entailed more turnover, and therefore more cleaning and inspection.

144. *Bloomberg* conducted its own investigation that corroborates these Former Employee reports. After a year-long investigation into the generic drug industry, *Bloomberg* reported that numerous former employees at Mylan's Nashik plant stated that "testing into compliance" was widespread at the Company, driven by pressure from the top to churn out large volumes of drugs. According to *Bloomberg*, these former employees explained that "investigating why a drug fails testing is time-consuming . . . whether due to time pressure, ignorance or just laziness," so it was often "easier to say the tester spilled some of the sample or made some other mistake and then test again." Then, if the batch passed the second test, "it was assumed to be fine." Likewise, Mylan employees also explained that because quality control teams "faced constant pressure to get the drugs out the door as fast as possible," it was "harder to properly investigate why a batch failed."

7. Following The 2016 Morgantown Inspection, Defendant Malik Privately Met With The FDA To Fend Off Further Agency Action

145. Following the Morgantown inspection, and unbeknownst to investors, the FDA privately wrote to Mylan demanding answers. The FDA noted that the agency's inspections "raised questions regarding the integrity and reliability of data generated" by Mylan's quality

control and assurance functions. As later reported in *Bottle of Lies*, Mylan privately responded to the FDA in January 2017 and attempted to explain away the agency's findings. But Mylan's explanations were vague, contradictory, and factually unsupported. For instance, Mylan told the FDA that one of the frequently occurring error messages at the Nashik plant the agency suspected was connected to Mylan's practice of "crashing files" was "not related to the disconnection of the Ethernet cable or power cord." The Company admitted in non-public correspondence, however, that "[i]t is not evident through retrospective review whether these disconnection events were caused by manual intervention of cables (accidental knocking of cables)" and failed to support its claim that any "knocking" of cables was "accidental." Similarly, Mylan vaguely ascribed another recurring error message—which was recorded 150 times in seven days—to a software setting that caused unintended consequences but was unable to provide a complete explanation to the agency.

146. The FDA rejected Mylan's excuses. As discussed above, on April 3, 2017, the agency publicly issued a warning letter, addressed to Defendant Malik, in connection with the Nashik plant. The Nashik warning letter summarized the CGMP and data integrity violations FDA inspectors had discovered, citing the Company's failure to "thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications." The FDA also highlighted the fact that analysts at the Nashik plant had "invalidated . . . initial failing result[s] without adequate investigation, performed re-testing, and then reported the . . . results of these replicate re-tests." The FDA required Mylan to develop a remediation plan under the supervision of a consultant.

147. The public, of course, remained unaware that the impetus for the Nashik inspection had been a whistleblower report detailing systemic CGMP and data integrity violations throughout Mylan, including the Company's flagship Morgantown facility. The public also was unaware that,

as the whistleblower reported, the FDA had indeed discovered that Morgantown was rife with the same profound product quality failures cited in the Nashik warning letter, including widespread "testing into compliance."

148. Defendants knew it was critical that they dissuade the FDA from also publicly issuing Mylan a warning letter concerning its key Morgantown facility. A publicly issued Morgantown warning letter would indicate that Mylan's CGMP and data integrity problems were not isolated to one or two plants in India, but were systemwide. As discussed above, if the FDA found that Mylan's product quality and data integrity issues were widespread, then penalties, sanctions, and remediation requirements could escalate dramatically. In addition, a Morgantown warning letter would further indicate to the public that these violations, were pervasive within Mylan's flagship manufacturing facility that was responsible for producing approximately 20 billion doses per year and was critical to its core U.S. operations. Accordingly, a public warning letter aimed at the heart of Mylan's U.S. operations would severely undermine Defendants' repeated statements touting the Company's "advanced" and "state-of-the-art" quality assurance and control processes as providing Mylan with a significant competitive advantage.

149. Mylan was already facing shareholder blowback over Congressional allegations of Medicare fraud and antitrust violations in connection with EpiPen, outsized executive compensation (including a $100 million payout to Mylan director Robert Coury), and high-profile acts of dishonesty by its leadership (including Defendant Bresch's misstatements about her academic qualifications). Indeed, on May 30, 2017—as Mylan was meeting with the FDA about Morgantown—a group of Mylan's major institutional shareholders issued a letter urging fellow investors to oppose the reelection of Mylan's directors at the Company's upcoming shareholder meeting. The letter accused the Mylan Board of reaching "new lows in corporate stewardship in

2016" in connection with "extraordinary and egregious" compensation paid to the Company's leadership that "came amid a public and regulatory backlash for the price-hiking controversy involving Mylan's EpiPen." A few weeks later, independent proxy advisory firm Institutional Shareholder Services ("ISS") also issued a report recommending that shareholders vote against reelection of most of Mylan's Board, including Defendants Malik and Bresch, because the Company's legal and regulatory exposure arising from the EpiPen scandal and alleged price fixing of generic drugs had caused "significant destruction in shareholder value." A public airing of Morgantown's egregious CGMP problems was the last thing Defendants needed.

150. Accordingly, in April 2017, less than three weeks after the FDA issued the Nashik warning letter, Defendant Malik and six other senior Mylan executives met with the agency to attempt to fend off further regulatory action, including a warning letter, directed at the Morgantown facility. Eban reported that at that meeting, FDA officials grilled Defendant Malik and the other senior executives about why Morgantown analysts had failed to investigate OOS and other anomalous test results and instead had retested the drugs and recorded passing results. As Eban reported, FDA representatives told Defendant Malik they were "stunned" by Mylan's "egregious" violations, which they said led the agency to question whether the Company was being "transparent at all of its sites."

151. The FDA's investigation made clear that the Morgantown facility was rife with the same egregious CGMP and data integrity violations discussed in the Nashik warning letter. Nevertheless, as discussed above, following the public issuance of the Nashik warning letter, Defendants downplayed it and concealed the widespread and systemic issues plaguing Mylan's far more significant Morgantown facility. Defendants claimed that the Nashik warning letter reflected discrete, one-off technical issues related to "evolving" FDA standards. Defendants also claimed

that the problems were confined to Nashik—"one of Mylan's 50 manufacturing sites"—and would not interrupt production or have a material impact on Mylan's business. Meanwhile, Defendant Malik continued to lobby the FDA in order to forestall a Morgantown warning letter. Defendant Malik emphasized Morgantown's importance to Mylan's business, assured the agency that the facility "was founded upon the principle of integrity," and blamed analysts' retesting without investigation on an old SOP that needed to be updated.

152. FDA staff in two separate divisions found Defendant Malik's explanations not credible and recommended further regulatory action to address Morgantown's CGMP non-compliance. As discussed above, the international investigators who visited the Morgantown site had rated Morgantown "Official Action Indicated," and the FDA had already drafted a warning letter sanctioning Morgantown. But that warning letter was never issued. Eban reported that in July 2017, over the strenuous objections of staff from both divisions, an FDA lawyer downgraded the investigators' findings from "Official Action Indicated" to "Voluntary Action Indicated." The same lawyer also decided to send an untitled letter to Mylan that was not visible to the public. Notably, this was the second time in two years this same lawyer had downgraded expert investigators' findings adverse to Mylan and concealed the agency's response, according to Eban. Yet, as Eban reported, even this lawyer acknowledged in an email to irate agency staff that the Company's improper retesting practices were "more widespread and that Mylan's investigation was insufficient."

8. Defendants Create A "Façade of Documents" Hoping To Appease The FDA

153. Defendants understood that Mylan's widespread data integrity issues, particularly those at Morgantown, were driven by the Company's emphasis on speed and volume. Meaningful and timely remediation of those failures would entail supply interruptions, reduction of volume,

and expensive plant remediation. As discussed above, however, Defendants were already facing intensifying shareholder displeasure and could not afford to publicly halt or reduce production at Mylan's flagship plant or announce that this key facility required an expensive makeover. Indeed, announcing a reduction in Mylan's generic portfolio or a halt in production at a key plant would be particularly damaging to Defendants, because, as discussed above, they had repeatedly touted Mylan's operational capacity as giving the Company a distinct competitive advantage in an era of generic drug price erosion. A public acknowledgment that Mylan's regulatory obligations made it difficult or impossible to maintain these competitive advantages would (and, at the end of the Class Period, ultimately did) push Mylan shareholders over the edge.

154. Instead, after prevailing upon the FDA to allow Mylan to voluntarily remediate Morgantown, Defendants made superficial changes designed to create the appearance of reform. As yet another whistleblower from inside the Morgantown plant later privately told the FDA in early 2018, Mylan's management, instead of working to remedy problems, was more focused on creating a "façade of documents" to fend off the agency. Eban reported that, according to the whistleblower, Mylan brought in a team of employees from India to rapidly close out a backlog of investigations into failing test results and defective products at Morgantown. Plant employees were told not to question their work. The whistleblower told the FDA that Mylan had developed an "embedded culture" of fraud and made no real effort to correct it.

155. Former Mylan employees corroborated the FDA whistleblower's account that Mylan did not actually address the underlying issues raised by the 2016 Form 483. For instance, FE1 "agreed completely" with the 2018 whistleblower's report that, following the 2016 Form 483, Mylan was more concerned with creating a "façade of documents" to give the appearance of regulatory compliance, than with remediating the facility's quality failures. FE1 reported that

during FDA inspections, Morgantown employees wrote, signed, and backdated SOPs to present to agency inspectors. Those "backdated" SOPs were created while the FDA was "waiting in another room," and included the language that Mylan believed the FDA wanted to see. Similarly, FE1 recalled that the "FDA would be in one hallway and [Mylan employees were] laying tape in the next hallway to segregate clean versus dirty equipment."

156. Following the issuance of the 2016 Form 483, FE1 attended meetings with senior Mylan personnel, including Morgantown Head of Quality Kupec and Senior Director of Quality Assurance Operations Koski, to discuss the FDA's findings. FE1 stated that the focus of the meetings was not about how to remediate the serious CGMP violation the FDA identified, but how to formulate a response defending the Company by the agency's deadlines. According to FE1, this was reflected by the fact that the meetings petered out not long after the Form 483 was issued. "We went from a couple meetings a day, to a couple a week, to none at all." In particular, FE1 reported that Mylan's practice of re-running tests until they passed was "definitely a topic of discussion" following the FDA's 2016 Form 483, but the Company made no real effort to address it. FE1 reported that the FDA's findings in the Form 483 were extremely serious: "In reality with that kind of report in this industry, the FDA would have been well within their right to deadbolt the door." Yet, FE1 reported, the Company's response was not serious.

157. Likewise, FE6 reported that Mylan failed to implement any significant remediation measures at Morgantown following the 2016 Form 483. Indeed, far from allocating additional money to Morgantown to finance meaningful remediation, FE6 reported that Defendant Malik, again, insisted on cuts to Morgantown's quality budget for 2017. FE6 explained that any remediation the site implemented would have to come out of its (now reduced) ordinary operating budget, which was already inadequate to meet the facility's quality compliance needs.

158. FE3 agreed with the 2018 whistleblower that Mylan was focused on creating a "façade of documents" to appease the FDA. FE3 reported that Mylan's remedial efforts following the 2016 Form 483 were essentially limited to addressing the manner in which observations were described in documentation, not to addressing the most egregious CGMP failures. FE3 stated that it was apparent from meetings with Morgantown's Quality Director that Mylan was anxious to avoid any remediation that would require the Company to halt production at the facility. FE3 stated that management was "afraid that if they got to heart of problem that would mean they had to stop testing." Because Mylan could not afford to halt production, it addressed only those superficial items that would not interrupt Morgantown's regular functioning.

159. FE2 echoed other Former Employees in this regard. FE2 reported that the Company did little in the way of remediation beyond changing some of its SOPs—efforts he described as "superficial." No real effort was made to remediate the enormous process and integrity failures that were widespread throughout the plant or address the overload of production volume at the core of those failures.

160. Similarly, FE8 was a Technical Area Lead in Manufacturing from 2016 to 2018. FE8 reported that Mylan made no real effort to address the issues identified in 2016 Form 483, despite the fact that employees recognized the issues raised by the FDA were serious and required substantial remediation. FE8 recounted that Defendant Malik held a town hall meeting at Morgantown in the first half of 2017. At this meeting, plant employees told Defendant Malik that Morgantown's quality function was stretched too thin and that the plant needed to increase its headcount in order to meaningfully address its CGMP compliance issues. Defendant Malik "immediately dismissed" these concerns. FE8 reported that remediation was not "taken seriously"

by Mylan management until after Mylan received another Form 483 directed at Morgantown in April 2018, as discussed below.

161. In this way, Mylan attempted to quietly spread out its remediation over a longer time-horizon and at least defer the most painful fixes until management was on better footing with investors. Defendants gambled that Mylan could appease the FDA long enough to avoid yet another painful and inopportune public disclosure of wrongdoing. All the while, Defendants continued to conceal the serious product quality problems afflicting the Morgantown plant, the scope and cost of required remediation, and the exponentiated risk of further adverse legal and regulatory consequences, including a warning letter or consent decree, if the FDA found that the Company had failed to timely address the deficiencies on its own.

162. However, Defendants continued to receive numerous warnings following the 2016 Morgantown inspection that the facility's product quality processes were woefully deficient. Indeed, between the start of the Class Period and the FDA's April 2018 inspection, Mylan issued recall notices for at least 15 different drugs and dosages manufactured at the Morgantown plant, including drugs referenced in the 2016 Form 483, for reasons that included: "Failed Dissolution Specifications; three month stability time point"; "Failed Impurities/Degradation Specifications: OOS results for known compound"; "Presence of Foreign Tablets/Capsules [in bottles]"; "Chemical Contamination: out of specification results for impurities were found to be the result of contamination of product from vapors associated with paint thinner used in repair of the manufacturing room"; and "Microbial Contamination of Non-Sterile Products."[5]

[5] Note that Mylan did not publicly report the drugs manufactured at each of its facilities and would not disclose this information even when asked by analysts. Among other things, Lead Plaintiff cross-referenced drugs identified in Mylan's Morgantown Form 483's with FDA recalls.

9. During Its March 2018 Morgantown Inspection, The FDA Found That Mylan's CGMP And Data Integrity Failures Were Still Widespread

163. In early 2018, the FDA received the whistleblower report discussed above. On March 19, 2018, the FDA, acting on that report, conducted another surprise inspection of the Morgantown plant. As in 2016, the investigative team was unusually large and sophisticated. The eight-member team included international experts, an FDA Center employee, and two chemists/biologists.

164. The FDA's investigators conducted a four-week inspection of the Morgantown plant and on April 12, 2018 privately issued a lengthy, scathing Form 483 addressed to Kimberly Kupec, Mylan's Head of Quality at Morgantown. The 2018 Form 483 cited the same egregious CGMP and data integrity violations about which the FDA had repeatedly warned Defendants and Mylan's senior leadership, including in the 2016 Form 483. Just as it did in 2016, the FDA concluded that the Morgantown facility's "[l]aboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity strength and purity." In total, the FDA made thirteen observations identifying specific categories of CGMP and data integrity violations at Morgantown facility, with multiple examples within each category.

165. Among other things, the FDA found that, just as in 2016, Mylan's practice of "testing into compliance" was still widespread at Morgantown, specifically finding that "[l]aboratory analyses are repeated until passing results are obtained." The 2018 Form 483 cited multiple instances involving several different drugs in which failures for cleaning verification tests were obtained, but equipment was "re-swabbed and re-analyzed" until the desired results were obtained. Moreover, the FDA found that even where Mylan opened an investigation, they were

frequently never closed out before the suspect drugs were released to the public, including many cases in which the Company observed "in-process results that were out of specifications."

166. Just as in 2016, Mylan continued to invalidate failing results and re-test drug products and equipment without adequate investigation. For example, investigators discovered that despite Mylan's high swab failure rate for cleaning "indicating that corrective action has not been effective," the Company failed to investigate the root cause of the repeated failures. Remarkably, failing swabs "were categorized as 'inconclusive' and invalidated if a re-swab in another location of the equipment yielded passing results."

167. Likewise, the 2018 Form 483 cited numerous instances in which Mylan dismissed failing results without investigating the batch failures, just as in 2016. For instance, Mylan received a complaint that drug tablets had a "high percentage of specks" on the surface yet failed to investigate whether they were caused by cross-contamination (notwithstanding the Company's chronic contamination and sanitation issues). Instead, Mylan dismissed the defect as "only on the surface" of the tablets, yet failed to inspect the interior of the tablets to determine whether this rationale was correct. In another example, Mylan received a complaint about dark blue spots on tablets, which contained trace metals associated with stainless steel. Mylan concluded that "likely point of introduction cannot be determined," yet never evaluated the equipment used in production as a potential contaminant.

168. Accordingly, FDA investigators once again concluded that Mylan "fail[ed] to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed."

169. In addition, and as in 2016, investigators found that Mylan made changes to batches without investigating the impact of the change or properly documenting it. Investigators noted

that one such changed batch was later subject to an investigation for "dissolution failure" and another for "excessive broken tablets."

170. And, again as in 2016, the FDA pointed out additional instances in which Mylan invalidated failing test results for apparently pretextual reasons. In one example, Mylan's Quality Unit attributed failing test results to the operators' lack of training, but this "was not supported by evidence because all involved operators were experienced." The Quality Unit failed to rule out defects in the drug but still released the batch. Likewise, the Quality Unit attributed failing test results to the fact that the analysis was conducted "outside . . . stability time range," but the data clearly showed the analysis was conducted well within the time range.

171. The FDA also found that the Morgantown facility was again failing to meet basic cleanliness requirements. Investigators reported that Mylan experienced dozens of visual cleaning failures, "for which a swab or an investigation were not performed" at all. Even where drug test failures were identified because of inadequate cleaning, Morgantown's managerial Quality Unit did not require equipment to be cleaned or product manufactured on the contaminated machine to be inspected.

172. As discussed below, the FDA ultimately issued a warning letter to Mylan arising out of the 2018 Morgantown inspection. The FDA was clear that Mylan had already warned that its re-testing practices were improper, writing that "the unjustified invalidation of failing test results is a repeat violation."

173. Importantly, the FDA investigators found that Mylan's management was responsible for Morgantown's egregious CGMP and data integrity failures. In the 2018 Form 483, investigators wrote that they "observed numerous instances of a lack of appropriate oversight by the Quality Unit and a failure to follow" Mylan's own operating procedures, which the Company

had submitted to the FDA. Significantly, the FDA excoriated "senior management" for failing to "ensure continuing suitability and effectiveness of quality systems through governance," including through a variety of management-level oversight organs, such as the "Trending Review Board, Annual Product Review," and "Quality Site Council," as, again, was required by Mylan's own operating procedures submitted to the agency. Among other things, management failed to review and approve changes in controls, equipment, and facilities.

174. Likewise, changes to written procedures were not reviewed and approved by management, as the Company's operating procedures required. Indeed, when pressed by investigators, the Quality Unit could not "provide a listing of all manufacturing changes made within the LIMS system [Mylan's "Laboratory Investigation Management System"] without a change control since November 2016 as these changes are not tracked reviewed or approved."

175. Moreover, the FDA found that "[d]rug product production and control records [were] not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed." Among other things, Mylan's Quality Unit "failed to review and close out all LIMS investigations" during the manufacturing process. Indeed, nearly 17% of the investigations opened in Mylan's tracking system were never closed out by the Quality Unit before the drugs were released to the public—many of those open investigations "were for in-process results that were out of specifications."

176. Finally, the FDA investigators cited additional data integrity violations, including a failure to develop "written procedures for production and process controls." The proliferation of additional violations corroborated the whistleblower's report that Mylan's data integrity problems had gotten worse, not better.

177. Significantly, in private correspondence with the FDA following the 2018 Morgantown inspection, Mylan acknowledged that the facility's profound CGMP failures were driven by the enormous volume the Company pushed through the facility. In the letter, Mylan's Head of Global Quality wrote, "We believe that the large volume of doses and products within the Morgantown portfolio, while it has enabled us to supply the US market with products manufactured in the US, has inhibited [Mylan's] ability to achieve the high level of control over our manufacturing processes that we expect." As numerous Former Employees, including FEs 1, 2, 4, 6, and 7 reported, this was well-known inside Mylan even before the start of the Class Period.

10. Following The FDA's 2018 Inspection, Mylan Was Forced To Halt Production At Morgantown, Dramatically Reduce Its Portfolio, And Implement Expensive Remedial Measures

178. In April 2018, after the FDA issued the 2018 Form 483, Defendants were finally forced to do what they should have done before the start of the Class Period. First, Mylan was forced to halt production at Morgantown while the Company's CGMP and data integrity processes were being remediated in order to protect consumers from adulterated products. FEs 2, 3, 6, and 8 confirmed that production at the Morgantown facility came to a stop following the 2018 Form 483. Second, Mylan was forced to dramatically reduce—by close to two-thirds—the overwhelming production volume that made it impossible to adequately perform mandatory quality control functions, including thoroughly testing all drugs and investigating failing results. Third, Mylan was forced to implement comprehensive remedial measures under consultant supervision and ensure those measures were validated and scalable before resuming production.

179. Mylan did not disclose any of these facts. Instead, on April 20, Mylan announced that it was laying off 15% of the employees at Morgantown. In a statement issued to news outlets announcing the layoffs, Mylan stated, "[W]e've realized that our Morgantown plant needed to be rightsized to be less complex. The right-sizing is consistent with discussions we are having with

the U.S. Food and Drug Administration and is necessary in order to position the site as best we can for continued operations."

180. In the weeks following the issuance of the 2018 Form 483, Mylan was also forced to recall numerous drugs manufactured at Morgantown. For instance, in the three weeks following the FDA's inspection, Mylan recalled at least seven different drugs and doses manufactured at Morgantown, including drugs that were flagged in the 2016 Form 483. The reason stated for the each of the recalls was "CGMP violations." Still, Defendants failed to disclose the Form 483, its findings, the halt in production, or Mylan's dramatic reduction in its generics portfolio. Through the remainder of the Class Period, Mylan continued to withdraw additional drugs and doses manufactured at Morgantown because of CGMP failures, defects, and contamination.

V. THE TRUTH EMERGES

A. June 27, 2018: Disclosure Of Morgantown Investigation And 2018 Form 483

181. On June 27, 2018, shortly before the market closed, *Bloomberg* issued a brief news alert reporting that, as described in ¶¶163-77 above, in the spring of 2018, the FDA had conducted a lengthy inspection into the Morgantown facility from March 19, 2018 to April 12, 2018. Specifically, *Bloomberg* reported that the FDA "made 13 observations" after inspecting Mylan's Morgantown plant, and that, among these observations, the FDA noted, "equipment and utensils not cleaned, maintained, and sanitized at appropriate intervals to prevent contamination that would alter the safety of the drug product." The 2018 Form 483 findings to which *Bloomberg* directed readers are described above in full.

182. Analysts understood that the FDA's conclusions were unusually serious. Cantor Fitzgerald's analyst wrote on June 29, 2018, "Our consultants agreed that the inspection was serious and not routine (maybe whistleblower). This is because there were 9 people at the inspection, and it took a long time to complete. The letter [2018 Form 483] was 32 pages, which

is quite lengthy. Also, the makeup of the inspectors was unusual. Inspectors are usually local, but this inspection included a national expert, FDA Center employee, and two chemists/biologists." Cantor also warned that the situation may be more dire than Mylan let on because a Form 483 "could turn into a Warning Letter or even a Consent Decree if the company does not address it in a timely and comprehensive fashion. This is because most of the observations could be summarized as quality control issues (not enough time or people addressing problems)."

183. On this news, Mylan's share price fell $1.12 per share, or approximately 3%, from $37.45 per share to $36.33 per share.

184. Defendants continued to conceal the full relevant truth and prevented the further decline of Mylan's stock price by continuing to make false statements and omit material facts about Mylan's purported commitment to quality. In response to *Bloomberg*'s disclosure of the Morgantown investigation and the FDA's issuance of the Form 483, Mylan issued a press release minimizing the impact of this development and reassuring investors that "Mylan is committed to maintaining the highest quality manufacturing standards at its facilities around the world," and "confident in the quality, safety and efficacy of our drug products."

185. The Company downplayed the Morgantown inspection as one of its regular inspections "by health authorities to ensure compliance," and noted that "the company has submitted a comprehensive response to the Agency and committed to a robust improvement plan." Mylan reassured investors that it would "continue to maintain a close dialogue with the Agency and is fully committed to working with FDA to address its observations." Again, Defendants failed to disclose that the FDA's inspection had forced Mylan to halt production at Morgantown, significantly reduce the Company's generics portfolio, and had materially increased operating costs.

B. August 8, 2018: Disclosure Of "Restructuring and Remediation Program In Morgantown"

186. On August 8, 2018, during Mylan's first earnings call since the public learned of the FDA's investigation at Morgantown earlier that spring, Defendant Malik disclosed that, at least in part due to its "robust . . . improvement plan" following the issuance of the FDA's 2018 Form 483, Mylan had "undertaken a restructuring and remediation program in Morgantown." This program included the "discontinuation of a number of products" and was "aimed at reducing complexity at the facility." Malik added that these measures "have temporarily had a negative impact on production levels, product supply and operations." Specifically, Defendants disclosed approximately $87 million in expenses related to the Morgantown restructuring and remediation program; a decline in total revenue of $2.8 billion or 5%; a 22% decline in North America revenue driven, in part, by "the impact of the restructuring and remediation program in our Morgantown manufacturing facility."

187. Nevertheless, Mylan's executives attempted again to minimize the disclosure and concealed material facts, assuring investors that the Morgantown restructuring "impact is temporary," that Mylan's "profitability levels are sustainable," that the "remediation and restructuring is going to be completely effective," and that "long term these actions will only further strengthen our Morgantown site." Defendant Malik specifically assured investors that the restructuring "was not triggered just by this FDA inspection. It was part of . . . this year's plan actually to right size it. Because we have observed that it will be very difficult for us to manage this sort of complexity which Morgantown has, which [sic] 20 billion doses, with evolving FDA expectations." Defendant Bresch added, "[W]e will be seeing that continued turnaround and us continuing to be able to re-bring volume back up to where we said we were bringing it back up to,

which is obviously streamlined from where the facility has been historically. So kind of that rightsizing and remediation is all happening simultaneously."

188. On this news, Mylan's share price fell $2.62 per share, or approximately 7%, falling from $39.23 per share to $36.61 per share.

189. Analysts reacted accordingly, taking the news of the Morgantown remediation and restructuring into account in their models but relying on Defendants' reassuring statements and remaining encouraged about the Company's outlook. Barclays' analyst stated, "Clearly MYL's initial print is a disappointment," noting that while "regulatory execution has been the limiting factor," "we believe MYL's US generic business has one of the deepest pipelines in the industry." Deutsche Bank updated its model for Mylan based, in part, on "gross margin pressure from remediation at [the] Morgantown facility," but noted, "While we lowered our estimates and target, we are reiterating our Buy rating. With the significant re-basing of the outlook, we are hopeful that MYL is shifting to a 'meet or beat' mode, which should be well received by investors if the company delivers." Deutsche Bank elaborated, "While the Morgantown remediation will have a temporary adverse impact on sale and margins, management expects longer-term benefits as it reduces complexity at the facility."

190. J.P. Morgan lowered its price target from $53 to $48 due, in part, to "remediation costs at the company's Morgantown facility (which appear more extensive than we had appreciated)," and to the fact that the restructuring "is having a larger-than-expected impact on results." Nevertheless, the J.P. Morgan analysts were still optimistic that "Mylan has commenced a strategic review as it looks to unlock value from its platform . . . . [W]e believe there are a number of paths for the company to unlock value from here." J.P. Morgan explained that although "Morgantown represents a larger headwind than we had anticipated for 2018 . . . the issues at

Morgantown appear manageable." BTIG's analyst also took comfort in Mylan's soothing statements, noting, "While Mylan does have more work to do at its Morgantown manufacturing facility[,] we think its remediation plan and restructuring will eventually lead to greater efficiency which should benefit the [company] down the road."

191. Several analysts were more skeptical. Morgan Stanley's analyst stated, "Morgantown facility issues disappointing. MYL disclosed significant operational issues which are negatively impacting business execution." And Wells Fargo expressed frustration with the Company, reporting, "Mylan's reported North American revenues (-22% YoY) were impacted negatively by the company's restructuring and remediation program at its Morgantown plant. We think it is important that Mylan explain further details on what caused the negative impact and how this was not anticipated. We believe whenever there is a significant headcount reduction in a manufacturing environment, there is always a potential for issues to emerge. As investors may recall, we published our takeaways on the layoffs at the Morgantown plant in April, but were only made aware of them through local press reports, not through direct communication from Mylan."

192. FiercePharma's August 9, 2018 reporting noted that worse times might be ahead for Mylan: "But besides the plant downsizing, the company is still having to address lots of shortcomings that the FDA laid out in two Form 483's in two years. The facility had been nicked in 2016 with a 23-page citation with five observations, some of them similar to those listed in the April report."

193. On November 5, 2018, however, Mylan held its earnings call for the third quarter of 2018 and further minimized the news of the Morgantown restructuring and its dramatic impact on Mylan's bottom line. Defendants attempted to regain investors' confidence by "celebrating the broad contribution" that the Morgantown restructuring has had on the business, claiming that this

development "may have been misunderstood by the investment community." Defendant Malik reminded investors that "we did not expect to have any significant new product launches from the site in 2019," and although the remediation program caused a "temporary disruption in supply of certain products for our customers and reduced volume in North America generic sales . . . . the value related to the rationalized product is not proportionate to the reduced volumes of those commoditized products."

194. In response to an analyst's question on "the impact the remediation is having on both your top and bottom line adjusted results as well as any more granularity on when in '19 we can expect the operations to begin to normalize at that facility," Defendant Malik dodged, reminding analysts that Mylan had purportedly "undertaken the remediation and restructuring . . . to keep this with the FDA's evolving standards" and to "rationalize and simplify the plant and reduce the complexity." By this point, however, the Company had disclosed that costs associated with the restructuring had reached $98 million.

C. November 9, 2018: FDA Warning Letter Concerning CGMP Violations At Morgantown

195. On November 9, 2018, the FDA issued a warning letter to Mylan in connection with the Morgantown facility, addressing the letter to Defendant Bresch. The letter, which was consistent with what the 2018 Form 483 previously disclosed, stated that it "summarize[d] significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals" that had been laid out in the Form 483 delivered to Mylan on April 12, 2018. The warning letter concluded, "Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of" federal law.

196. The Morgantown warning letter summarized the CGMP and data integrity violations FDA inspectors had discovered, citing the Company's failure to "thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications." Specifically, the warning letter stated that Mylan's "investigations into out-of-specification (OOS) results and process deviations were inadequate. Root causes did not consistently include scientifically supported conclusions." Instead, the warning letter reiterated that failing drugs and equipment were simply retested until passing results obtained, as both the 2016 and 2018 Forms 483 had made clear to Defendants.

197. For instance, the warning letter stated that failing results were repeatedly attributed to "untrained or inexperienced operators," but the Company failed to investigate obvious deficiencies in the Company's manufacturing process, as numerous Former Employees reported. The FDA pointed out that as a result of this improper practice, Mylan was forced to recall "all batches of prednisolone sodium phosphate ODT within expiry from the U.S. market" on April 30, 2018. Mylan failed to disclose these facts to investors even as it continued to tout the Company's manufacturing processes and quality control.

198. In another example, Mylan had "opened multiple manufacturing investigation reports and trending assessments from July 2016 to October 2017 related to out-of-trend and OOS content uniformity results for metolazone 2.5 mg tablets." Despite the fact that no root cause for these failing results had been identified, no remedial plan had been implemented, and the Company continued to observe "substantial non-uniformity . . . in multiple batches" of the drug, Mylan "continued to manufacture and release this drug product up to the time of the inspection" in April 2018. Once again, this stunning disregard for product quality and safety occurred during the period

following the 2016 Morgantown inspection, in which Malik assured the FDA that Mylan would address the facility's CGMP deficiencies.

199. The FDA's findings left no doubt that Mylan's senior management was responsible for the profound and widespread CGMP failures at Morgantown. Contrary to Defendants' repeated statements touting the Company's robust quality assurance processes, the warning letter explained, "Your firm lacks an adequate ongoing program for monitoring process control to ensure stable manufacturing operations and consistent drug quality."

200. The warning letter targeted Mylan management's failure to adequately institute controls at the Company to address deficiencies in Mylan's production protocols, noting, "When significant variability is observed in one or more stages of pharmaceutical production, it is essential for executive management to support and implement effective actions that proactively address the source(s) of the variation and provide for a continued state of control."

201. The FDA made clear that it was management's CGMP compliance failures that were driving widespread product quality failures at Morgantown: "Your lack of rigorous oversight of manufacturing changes continues to be a major factor in the unexpected variation observed in your drug products."

202. Significantly, the FDA made clear that the CGMP and data integrity issues identified in the warning letter and in the 2018 Form 483—including "invalidating numerous initial OOS assay results without sufficient investigations to determine the root cause of the initial failure"—were "repeat violations at multiple sites" about which the FDA had warned Mylan on several occasions. Specifically, the warning letter stated that the FDA previously "cited similar CGMP violations at this and other facilities in your company's network." As examples, the FDA cited a 2015 warning letter issued in connection with three Mylan facilities in India as well as the

2017 Nashik warning letter, both of which warned Mylan about its "fail[ure] to thoroughly investigate unexplained discrepancies" and "invalidat[e]" numerous "initial out-of-specification (OOS) assay results without sufficient investigation to determine the root cause of the initial failure."

203. The FDA concluded in the warning letter, "These repeated failures at multiple sites demonstrate that Mylan's management oversight and control over the manufacture of drugs is inadequate . . . . Your executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance."

204. On November 20, 2018, the FDA posted the warning letter on its website and FDA Commissioner, Dr. Scott Gottlieb, took the unusual step of reporting the Warning Letter on Twitter. Posting a direct link to the Warning Letter, Commissioner Gottlieb tweeted, "An important aspect of ensuring drug safety is adherence to current good manufacturing practices. Recently #FDA issued a warning letter to Mylan Pharmaceuticals for CGMP violations. We expect the firm to work to resolve the issues identified by the #FDA."

205. In a November 20, 2018 press release responding to FDA letter, Mylan admitted that it had discontinued production of some products at the Morgantown site and transferred production of some to other sites. "These actions have led to a temporary disruption in supply of certain Mylan products for customers," Mylan said. "We understand that this current and temporary situation puts a burden on our customers and appreciate their ongoing confidence in Mylan. We will continue to work closely with our customers to mitigate any possible supply disruptions and meet the needs of the patients we serve."

206. In a January 18, 2019 analyst note, Leerink responded to the news of the FDA's warning letter to Mylan regarding the Morgantown plant. Leerink's analysts consulted a CGMP

specialist, who was "not surprised that Mylan received a warning letter," given the "severity" of the CGMP failures cited by the FDA. Leerink's specialist noted that the FDA's observations "raise concerns around patient safety and product quality and thus will require extensive actions to correct."

D. February 26, 2019: Disclosure of 18% Decrease In Net Sales Due To Morgantown Restructuring

207. On February 26, 2019, Mylan released its financial results for the fourth quarter and full year of 2018. The Company reported total quarterly revenues of $3.08 billion and yearly revenues of $11.43 billion, a decline of 5% and 4%, respectively, compared to the prior periods. The Company also disclosed North American segment net sales of $1.10 billion, down 16% for the quarter and 18% for the year, "primarily due to lower volumes on existing products, which was primarily driven by actions associated with the restructuring and remediation activities at the Morgantown plant."

208. Contrary to Defendants repeated reassurances during the Class Period, Bresch disclosed that, to remediate Mylan's CGMP deficiencies, the Company had "rationalized the significant portion of our commodity generics business," including three of the Company's highest margin products. Likewise, Defendant Malik disclosed on Mylan's earnings call that, "As part of our Morgantown remediation and restructuring activities and accelerated commoditization of oral solids, we discontinued almost 250 SKUs of highly commoditized oral solid products."

209. Defendant Malik elaborated further on Morgantown on the earnings call:

> After the April 2018 inspection and receipt of a 483 form, the company took a comprehensive restructuring and remediation of the Morgantown plant to address the issues that had been identified. Notwithstanding these efforts, the company received a warning letter related to the previously disclosed observations in the fourth quarter. The issues raised in the warning letter are being comprehensively addressed. The Morgantown plant continues to supply products for the U.S. market while we execute on and assess the restructuring and remediation activities.

210. Defendant Malik stated further:

> No significant new product revenue is forecasted from the Morgantown plant in 2019. Also, we look at our business in North America. Only 5 of our top 50 gross margin-generating products are currently manufactured in Morgantown. We remain committed to maintaining the highest-quality manufacturing centers at our facilities around the world and to continuous improvement in a time of evolving industry dynamics and regulatory expectations.

211. Defendant Parks also disclosed that remediation costs had reached $258 million.

212. In response to this news, Mylan's share price fell $4.61 per share, or approximately 15%, from $30.62 per share to $26.01 per share.

213. During the earnings call, Defendant Malik attempted to reassure analysts that the impact of the remediation was already beginning to recede and that the effects of the remediation were minimal. BMO's analyst asked, "So regarding the remediation at Morgantown, how far will that stretch into 2019? I want to understand better what [is] still involved and how long it will persist." Defendant Malik responded:

> [W]e continue to execute and assess our restructuring and remediation activities at the site through this 2019. And of course, we are focused on meeting our commitments to FDA as well as customers. Now as far as any negative financial impact on the business, I think we don't see that anymore as we go into 2019. As I've mentioned, it's, I think, largely behind us. We continue to supply from Morgantown our key products. . . . [T]here's no new big launches or no new launches. But still in 2019, from Morgantown and also from the materiality point of view, only 5 out of our top 50 North American products today come from Morgantown.

214. Defendant Bresch also attempted to attribute the Company's disappointing results to ongoing price erosion in the generics industry, noting that Mylan's ability to undertake new product launches (rather than, as she had claimed in 2017, having a large portfolio) would help Mylan combat erosion: "And I think that as we look forward, we're kind of still seeing that mid-single-digit erosion. I think the biggest difference for us is having the product—new launches be

able to offset that erosion, and that's really been historically what has meant success in this business."

215. The market was disappointed by these disclosures. J.P. Morgan's February 27, 2019 analyst report stated that Mylan's news was even worse than the firm expected: "While there were low expectations heading into today's results, Mylan's 2019 earnings guide was well below our/Street expectations (~$5.00 consensus. $3.80-4.80 guide), and we are lowering our estimates and price target for the stock." *Bloomberg*'s February 27, 2019 report was similarly pessimistic, noting, "Mylan NV fell by the most in three years on Wednesday, despite vows from executives to do 'everything and anything' to reverse the generic-drug maker's flagging fortunes as it nears the end of a strategic review." *Bloomberg* continued, "[Mylan] has also had manufacturing problems at a major manufacturing plant in Morgantown, West Virginia, which contributed to a 16 percent drop in North American sales."

216. Nevertheless, analysts continued to credit Defendants' soothing statements. BMO noted on February 27, 2019, "Morgantown remediation ongoing but disruption is largely behind them and facility continues to supply key products (no new major launches from there in 2019)." And Leerink reported the same day, "Morgantown remediation efforts continue to progress, management believes the negative impact is in the rear-view mirror. Management indicated it continues to address the issues related to the Warning Letter. The plant continues to supply products, but no significant new product revenue from here is forecasted in 2019 and only 5 of the top 50 gross margin products come from the facility. Management doesn't anticipate additional negative financial impact progressing later through this year."

E. May 7, 2019: Disclosure Of Q1 2019 Loss Due To Morgantown Restructuring

217. Finally, on May 7, 2019, Mylan reported a surprise loss for the first quarter of 2019 due, in significant part, to additional costs associated with the Morgantown restructuring. Mylan

reported that its revenues and earnings-per-share were down year-over-year by 7% and 15%, respectively, driven by Mylan's discontinuation of numerous products manufactured at Morgantown. Mylan also reported that its quarterly adjusted free cash flow had materially declined, which, on Mylan's earnings call, Defendant Bresch attributed to, among other factors, "the Morgantown remediation." In response to an analyst question about "the magnitude of the Morgantown remediation" and specifically its "impact on volumes," Mylan's Chief Operating Officer acknowledged, "we had done a number of discontinuations throughout 2018, over 100 SKUs that we had discontinued as part of a process to continue to prune our portfolio. And that certainly has played a big role in how much we've seen year-over-year volume declination." Defendant Parks elaborated that the declines in Mylan's North American business were "primarily driven by lower volumes due to changes in the competitive environment and the impact of the Morgantown plant remediation activities, and to a lesser extent negative pricing impacts."

218. Defendants also disclosed an additional $69.9 million in expenses stemming from the Morgantown restructuring.

219. On this news, Mylan's share price fell $6.73 per share, or approximately 24%, from $28.26 per share to $21.53 per share.

220. Analysts were shocked at the extent of the impact Mylan's remediation program at Morgantown was having on the Company's business. Cantor Fitzgerald's May 7, 2019 report noted, "Takeaways from the quarter: 1) North America segment net sales of $922.9MM, down 6% on an actual and constant currency basis, primarily driven by changes in the competitive environment and the impact of the Morgantown plant remediation activities." RBC's note the same day described that any gains in market share for certain drugs "were offset by lower overall volumes (including the impact of the Morgantown remediation activities) and lower pricing."

Leerink explained, "Additional takeaways: (1) Weakness in North America (-6% Y/Y) was driven by lower volumes on existing products, primarily driven by changes in the competitive environment and the impact of the Morgantown plant remediation activities, partially offset by new product sales," and hoped for "additional color from management" on . . . the progress of the remediation efforts for the Morgantown facility." UBS's May 7, 2019 note reported, "[M]anagement stated that volumes were down due to competitive pressures and remediation activity of the Morgantown plant. We'll look for more color on the call regarding the status of the remediation and its expected impact." Zacks' May 22, 2019 report described, "Mylan's first-quarter earnings beat estimates, but sales missed the same due to currency headwinds. North America continues to witness challenges due to changes in the competitive environment and the impact of the Morgantown plant remediation activities."

221. As the relevant truth emerged about Mylan's CGMP and data integrity violations—and the attendant effects of these failures on the Company's bottom line—Mylan's share price plummeted by over 50%.

VI. SUMMARY OF ALLEGATIONS THAT DEFENDANTS KNOWINGLY OR RECKLESSLY MISLED INVESTORS

222. As alleged in this Complaint, numerous facts give rise to the strong inference that, throughout the Class Period, the Defendants knew or recklessly disregarded that their statements and omissions were materially false and misleading when made. The information in this section summarizes certain of the allegations—that are set forth more fully above—that detail the Defendants' scienter.

223. First, Defendants received numerous direct warnings, both before and during the Class Period that Mylan's quality assurance processes at the Morgantown facility were dangerously deficient and that the site was rife with serious, widespread CGMP and data integrity

failures. For instance, as alleged above, the FDA privately sent Mylan a Form 483 in November 2016 detailing numerous egregious CGMP and data integrity violations at Morgantown that directly contradicted Defendants' public statements. Among other things, the FDA's 2016 Form 483 warned Defendants that Mylan:

- Routinely "tested into compliance" by repeatedly re-testing drug products that had failed quality testing in order to achieve passing results without any legitimate investigation into the cause of the initial failure;
- Repeatedly misstated investigative findings;
- Altered drug samples;
- "Improperly invalidated" reports of defects and failing quality testing results; and
- Engaged in a host of suspect data practices, including "pre-injecting" batch samples, designed to avoid recording failing quality testing results and triggering costly production delays and recalls.

Again, as alleged above, and as Defendants were well-aware, these CGMP and data integrity violation, including Mylan's improper practice of testing into compliance, were extremely serious and required remediation. This remediation historically entailed severe disruptions to production and increased operating costs for extended periods.

224. Even after the FDA privately issued Mylan the 2016 Form 483, Defendants continued to receive clear warnings from the FDA that Morgantown suffered from severe quality control issues. For instance, in April 2017, Defendant Malik attended a private meeting with the FDA, at which agency officials directly told him that they were "stunned" by Mylan's "egregious" violations, which they said led the agency to question whether the Company was being "transparent at all of its sites." Indeed, Defendant Malik only prevented the FDA from issuing a warning letter that would publicly reveal Morgantown's CGMP deficiencies by committing Mylan to extensive remediation, which, as alleged above, the Company failed to implement. Indeed, as FE6 reported, Defendant Malik not only failed to allocate additional resources to Morgantown to

finance the extensive remediation that the plant clearly required, but he insisted on cuts to the facility's budget.

225. Moreover, during the Class Period, Mylan was forced to recall numerous drug products manufactured at Morgantown, including drugs cited in the FDA's 2016 Form 483. Between the start of the Class Period and the FDA's April 2018 inspection, recall notices were issued for at least 15 different drugs and dosages manufactured at the Morgantown plant, including drugs referenced in the 2016 Form 483, for reasons—such as evidence of cross-contamination and OOS manufacture—that made clear to Defendants that the CGMP failures about which they had been privately warned in the 2016 Form 483 remained widespread and continued to affect production at the facility.

226. In the spring of 2018, Defendants received another clear and unambiguous warning that Morgantown was rife with serious CGMP and data integrity failures. On April 12, 2018, following an inspection prompted by a whistleblower report of continued fraud at Mylan, the FDA issued yet another scathing Form 483 to Mylan citing the same egregious CGMP and data integrity violations about which Defendants and other members of Mylan's senior leadership had been repeatedly warned, including in Morgantown's 2016 Form 483. Among other things, the FDA found that Mylan's improper practice of invalidating failing results and retesting drug products without adequate investigation was still widespread. As a result of the FDA's findings, Defendants were forced to halt production at Morgantown, dramatically reduce Mylan's generics portfolio, and implement an extensive CGMP remediation program. Yet, even at this point, Defendants continued to tout the Company's robust assurance processes and its vast operating capacity and conceal the truth from investors.

227. Indeed, Defendants only disclosed the FDA's 2018 Form 483 when forced to do so, after *Bloomberg* issued a short blurb reporting on the FDA's inspection. Again, however, Defendants failed to disclose the significant production disruptions or increased operating costs roiling the Company's operations, and, instead, issued misleading soothing statements to spin the adverse news and quell investor concern.

228. Even before the start of the Class Period, Defendants received numerous warnings of pervasive data integrity violations at Morgantown. For instance, in 2009, the *Pittsburgh Post-Gazette* reported that employees routinely engaged in a host of improper practices designed to evade the FDA's quality regulations, including "crashing files." As alleged above, Defendants not only vigorously and falsely denied the newspaper's allegations, but also sued the *Post-Gazette* in order to silence further reporting on these issues.

229. Second, that Defendants were charged with ensuring the adequacy of Mylan's quality assurance processes and regularly received information about the state of the Company's CGMP compliance supports an inference of scienter. As alleged above, Mylan submitted an internal "SOP"—standard operating procedure—to the FDA. Mylan's SOP provided that "Senior Management," together with the Company's Quality Council, was responsible for "ensuring" Mylan's quality control and CGMP compliance by, among other things, closely monitoring detailed information on these subjects it received from a variety of oversight organs and programs. Specifically, Mylan's SOP states that Mylan's Quality Council "along with Senior Management" must "ensure continuing suitability and effectiveness of quality systems through governance including but not limited to Trending Review Board, Annual Product Review, Self-Inspection, and Quality Site Council."

230. In fact, as alleged above, Mylan touted management's close oversight of the Company's quality control and CGMP compliance processes in its statements to investors, including specifically through detailed data it received from the Quality Council. For instance, in a 2018 report, Mylan assured investors that it had "global systems and processes in place to provide our people with the foundation and tools needed to maintain an effective quality management system . . . . Our Quality Council program provides management with clear, quantitative data, including that of key performance indicators. It also tracks and analyzes quality trends, reviews inspection results and identifies potential areas for employee training." Accordingly, Defendants either exercised the oversight they claimed, in which case they were amply informed about Morgantown's CGMP failures, or they failed to exercise that oversight, in which case their statements were reckless, at a minimum.

231. Moreover, Defendants had additional access to data relating to failed quality control testing through Mylan's TestTrack system. As alleged above, data relating to failed quality testing results were contemporaneously recorded in TestTrack, and showed, among other things, an enormous backlog of unresolved investigations, repeated invalidation of failing results for stock reasons (such as "dirty glassware"), and repeated re-testing of failing results without documentation of any investigation into the failures.

232. Third, the egregiousness, scope, and duration of Morgantown's CGMP and data integrity failures supports an inference of scienter, particularly since the FDA had warned Mylan that the very same violations affected other Company facilities. As alleged above, Mylan's improper quality testing and assurance practices contravened core CGMP regulations and industry standards, notwithstanding Defendants' assurances that Mylan's facilities were not only meeting, but exceeding, both. As both the FDA and commentators have explained, Mylan's CGMP failures

were not minor or arcane, but, rather, were blatant and pervasive, and, therefore, could not reasonably have escaped management's notice. And as FDA whistleblowers and Former Employees explained, these glaring deficiencies were pervasive throughout Morgantown, and throughout several other Mylan facilities, for years, even before the start of the Class Period.

233. In meetings with, and reports issued to, Mylan, the FDA characterized the Company's CGMP violations as "egregious," "stun[ing]," and "significant," and told Defendant Malik that they led the agency to question whether the Company was being "transparent at all of its sites." Following public disclosure of Morgantown's CGMP failures, analysts and industry commentators likewise noted the violations were exceedingly serious. For instance, Leerink analysts stated in a January 2019 report that the CGMP failures cited by the FDA "raise concerns around patient safety and product quality and thus will require extensive actions to correct" and that a specialist they consulted noted "the severity" of the violations and "was not surprised that Mylan received a Warning Letter."

234. Indeed, Mylan did not merely perform shoddy or subpar quality testing at Morgantown; it failed to perform any quality testing of at least 95% of the drug products manufactured there and, in many cases, tested equipment no more than once a year, directly contrary to Defendants' public statements.

235. Likewise, Mylan did not merely ignore quality assurance standards, it actively bypassed and subverted key FDA-mandated safety testing. For instance, the FDA repeatedly warned Defendants that Mylan routinely tested drug products and equipment into compliance at Morgantown, in contravention of numerous well-established regulatory requirements and long-standing agency guidance singling this practice out for censure as "unscientific and objectionable under CGMPs." Similarly, the FDA warned Mylan that the Company had engaged in a host of

suspect data practices, including repeatedly misstating investigative findings, altering drug samples, "improperly invalidat[ing]" reports of defects and failing quality testing results, and "pre-injecting" batch samples. Indeed, Mylan itself acknowledged in private correspondence with the FDA that the agency's 2016 findings "raised questions regarding our laboratory testing and the validity of the data generated to support our product on the market." As Mylan well knew, other drug makers found to have similarly violated data integrity requirements were required to undergo extensive remediation and suffered severe business disruptions as a result. Indeed, these violations were so serious that the FDA's Commissioner took the unusual step of personally tweeting out the FDA's 2018 warning letter to Mylan recounting some of them.

236. Further, as the FDA pointed out, Mylan's CGMP and data integrity failures were extremely serious because they demonstrably jeopardized patient safety, leading to the release of adulterated and contaminated drug products to the public. Indeed, as discussed above, Mylan was forced to recall dozens of drugs manufactured at Morgantown during the Class Period as a direct result of the Company's egregious CGMP and data integrity failures.

237. In addition, as the FDA also repeatedly made clear, Mylan's "senior management" was directly responsible for, and implicated in, the Company's CGMP failures. In the 2018 Form 483, the FDA excoriated "Senior Management" for failing to "ensure continuing suitability and effectiveness of quality systems through governance" and cited "numerous instances of a lack of appropriate oversight by the Quality Unit and a failure to follow" Mylan's own operating procedures. Likewise, the Morgantown warning letter explained, "Your firm lacks an adequate ongoing program for monitoring process control to ensure stable manufacturing operations and consistent drug quality . . . . When significant variability is observed in one or more stages of pharmaceutical production, it is essential for executive management to support and implement

effective actions that proactively address the source(s) of the variation and provide for a continued state of control . . . . Your lack of rigorous oversight of manufacturing changes continues to be a major factor in the unexpected variation observed in your drug products." Similarly, Leerink analysts noted in their January 2019 report that the specialist they consulted "was not surprised that Mylan received a Warning Letter especially given that inadequacies of the quality control unit was designated as Observation #1."

238. As the FDA pointed out, Mylan had received repeated warnings about these same serious violations—including widespread testing into compliance—at several other facilities, including Nashik and at least three other sites Mylan had acquired prior to the Class Period. These allegations support an inference that, at a minimum, Defendants recklessly disregarded that these serious CGMP failures pervaded Morgantown, one of the Company's most significant manufacturing sites. As the FDA concluded in the Morgantown warning letter, "These repeated failures at multiple sites demonstrate that Mylan's management oversight and control over the manufacture of drugs is inadequate . . . . Your executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance."

239. Accordingly, the magnitude and pervasiveness of the deficiencies in Mylan's quality control processes and CGMP compliance, and the length of time those deficiencies went unaddressed, further support an inference that Defendants' repeated statements touting the Company's quality control processes and manufacturing capabilities were made either in a deliberate attempt to deceive or in reckless disregard of obvious facts.

240. Fourth, Morgantown's profound CGMP failures were pervasive and widely known throughout Mylan, which supports an inference of Defendants' scienter. As described above, numerous Former Employees and FDA reports not only confirmed that the CGMP and data

integrity failures that the FDA identified at the Company were egregious and systemic, but also that they were widespread throughout Mylan's facilities and widely known by Company personnel. For instance, FE6 reported that even prior to the start of the Class Period, senior Mylan executives, including Mylan's Vice President of Operations, the Head of the Morgantown facility, and the Heads of Quality and Manufacturing at Morgantown, knew and routinely discussed that it was impossible for Morgantown to both meet the facility's outsized production demands and satisfy its CGMP compliance and product quality obligations.

241. Likewise, FE1 recalled reporting both Morgantown's failure to test the majority of its manufactured drugs and equipment and Mylan's practice of "testing into compliance" to his superiors, including Morgantown's Head of Quality, Kim Kupec, and the Senior Director of Quality Assurance Operations, Eddie Koski, in meetings in 2015 and 2016, but his concerns were ignored. FE2 similarly described that, from prior to the Class Period until April 2018, testing into compliance was widespread at the Morgantown facility and conducted at the express direction of his supervisors in the Quality Assurance division. FE4 also described the practice of "testing into compliance" as "commonplace" throughout Mylan during his tenure with the Company. FE5 noted that the practice of testing into compliance was not only prevalent at Morgantown, but also at Mylan's sites in Nashik and Bangalore, India.

242. Former employees similarly described other suspect practices—including "pre-injecting" data samples and "crashing files" to avoid recording bad results—as widespread throughout Mylan's facilities. FE1 explained that improperly re-injecting drug samples into gas chromatographs prior to official analyses was a widespread practice at Morgantown, which continued but "became more covert" after the FDA issued the 2016 Form 483. FE1 also explained that employees at Morgantown consistently cut the power to their computers to crash them when

their computers showed that analyses were failing; this practice allowed analysts to void any record of a failing test result. FE2 confirmed that he and other technicians received instructions from their supervisors to abort analyses this way when OOS results were imminent.

243. Mylan former employees have also explained that instances of cross-contamination and egregious cleaning violations were widespread and numerous throughout Mylan's facilities. FE1 recalled repeatedly raising issues of cross-contamination—in which drugs were contaminated with residue from drugs previously manufactured on the same equipment—with his superiors, but no meaningful remedial measures were ever implemented. FE3 agreed, noting that because Mylan failed to test the vast majority of the drug products manufactured at Morgantown, numerous rooms within the facility were visibly cross-contaminated (which the FDA also observed and cited).

244. Finally, former employees of Mylan have described that it was common knowledge within the Company that Mylan's overwhelming production volume prevented Morgantown personnel from meaningfully investigating failing quality tests. For instance, FE3 explained that only 3% to 5% of the drugs manufactured at Morgantown were actually subject to product quality testing during his tenure because the enormous production volume flowing through the facility made more comprehensive testing impossible. FE1 agreed, reporting that, beginning in the late 2000's and through the remainder of his tenure at the Company, Mylan performed product quality testing on no more than 5% of the drugs manufactured at Morgantown because production demands made broader testing impossible. FE4 similarly described that, because Mylan's production volume was so high, Morgantown personnel lacked the time and resources to meaningfully investigate failing quality tests. In fact, at the close of the Class Period, Mylan's Head of Global Quality admitted to these widespread failings, writing in a letter to the FDA following the 2018 Form 483, "We believe that the large volume of doses and products within the

Morgantown portfolio, while it has enabled us to supply the US market with products manufactured in the US, has inhibited [Mylan's] ability to achieve the high level of control over our manufacturing processes that we expect."

245. Fifth, Mylan's quality control processes and CGMP compliance were an area of significant regulatory scrutiny, which further supports an inference of Defendants' scienter. As described above, because Mylan is subject to strict regulatory control, Defendants were familiar, and had extensive experience, with the FDA's inspection and citation process. As discussed above, the FDA inspected Mylan's facilities and inspectors reported regulatory violations to Mylan's management. In particular, and as Mylan knew, enforcement of data integrity standards was a subject of outsized concern at the FDA at the outset of the Class Period. As alleged above, the FDA has emphasized that companies that violate CGMP and data integrity requirements face severe sanctions. Moreover, several drug manufacturers found to have violated data integrity requirements, including the FDA's clear proscriptions against testing into compliance, have experienced serious adverse consequences as a result. These consequences included severe and prolonged production disruptions, significantly increased operating costs driven by extensive remediation requirements, and freezing of new drug approvals.

246. The experience that Mylan's executives had with the FDA's inspection and citation process—which consistently resulted in findings of CGMP and data integrity violations across numerous Mylan facilities and the issuance of citations to the Company—supports the inference that Defendants' statements regarding Mylan's compliance with CGMP and data integrity regulations were at least recklessly false when made.

247. Sixth, the significance of the Morgantown facility to Mylan's profitability, operational capacity, and overall financial wellbeing supports an inference of Defendants' scienter.

The Morgantown campus is Mylan's largest and most significant facility in the United States; in fact, it is one of the largest pharmaceutical manufacturing facilities in the entire United States. Mylan highlighted Morgantown as a "significant" manufacturing facility in its Forms 10-K filed throughout the Class Period. In a January 2019 analyst report, Leerink noted that the Morgantown facility produced approximately 85% of the oral solid doses of drugs (the dominant form of dosage) Mylan sold in the United States, approximately 17 billion doses. Indeed, Defendant Malik has personally admitted that Morgantown was "significant for us." The fact that the egregious CGMP and data integrity violations described in this Complaint were, for years, rampant at Mylan's largest and most significant manufacturing facility—the plant producing the vast majority of the drugs Mylan sold—supports the inference that Defendants' statements and omissions minimizing or outright hiding those CGMP and data integrity violations were knowingly false when made.

248. Seventh, that Defendants' false and misleading statements about Mylan's product quality and operating capacity concerned one of the most significant issues and gravest risks facing the Company during the Class Period further bolsters the inference of scienter. As alleged above, CGMP and data integrity compliance was essential to Mylan's ability to market its drugs and, therefore, of critical importance to investors. As discussed above, the FDA has repeatedly warned that companies violating CGMP and data integrity standards face severe sanctions. Moreover, numerous drug makers found to have violated these have experienced significant disruption to production, product approval, and greatly increased operating costs driven by expensive remediation. Indeed, Mylan itself acknowledged that "[f]ailure to comply with CGMP" could result in a host of adverse regulatory and business consequences, including "warning letter[s], fines, penalties, disgorgement, unanticipated compliance expenditures," product recalls, and even

criminal prosecution. Accordingly, Defendants issued numerous public statements touting Mylan's rigorous product quality processes as a key "strength," value driver, and competitive advantage. And when news of the Nashik warning letter became public, analysts and investors sought, and received, numerous reassurances from Defendants about Mylan's CGMP compliance.

249. Likewise, in direct response to analyst questions throughout the Class Period about how Mylan was weathering an unfavorable pricing environment, Defendants repeatedly—almost unfailingly—cited the Company's vast operating capacity as a key differentiator that allowed the Company to attract customers and react opportunistically to market shortages. For instance, at the June 2016 Goldman Sachs Healthcare Conference, Defendant Bresch told investors, "It's always been a volume-driven business, always . . . . [T]here's a much—more of a sense from our customer base that having a reliable global supply chain is important, that they don't want to have to turn customers away because of products—they're not able to get their hands on a product." Thus, the integrity of Mylan's operating platform and the Company's ability to reliably produce industry-leading volume "all to stringent quality standards," as Defendants claimed was of utmost importance to investors.

250. Accordingly, the fact that Defendants' misstatements concerned some of the most significant issues and risks facing Mylan during the Class Period, supports an inference of severe recklessness at a minimum, particularly given the numerous warnings concerning egregious CGMP failures Defendants received.

251. Eighth, Defendant Malik's experience and tenure at Ranbaxy—a generic drug manufacturer that was rocked by scandals stemming from CGMP and data integrity violations that mirrored those that plagued Mylan during the Class Period—supports an inference of Defendant Malik's scienter. Throughout a seventeen-year career at Ranbaxy, Defendant Malik was intimately

involved in Ranbaxy's CGMP and data integrity violations. As described above, shortly after Defendant Malik's departure from Ranbaxy, a whistleblower reported to the FDA that the company had fabricated data concerning 200 products sold across 40 countries over the course of two decades—Defendant Malik's entire tenure at the company—and that the company's practice of forging data, lying to regulators, and endangering patients was "common knowledge" within the company. The whistleblower's report led to an FDA investigation, an armed raid on Ranbaxy's New Jersey headquarters, and the issuance of two warning letters to Ranbaxy. This supports the inference that Defendant Malik was instrumental in fostering the culture at Mylan under which such failures became the norm. At the very least, Defendant Malik was reckless in turning a blind eye to the growth of such a culture: as his experience at Ranbaxy makes clear, Defendant Malik knew CGMP and data integrity failures when he saw them.

VII. DEFENDANTS' FALSE AND MISLEADING STATEMENTS

252. As summarized in detail below, throughout the Class Period, Defendants Mylan Bresch, Malik, and Parks each made materially false and misleading statements and omissions concerning: (i) Mylan's quality assurance process and efforts to comply with CGMP and data integrity standards; and (ii) Mylan's "broad" operating capacity and the lack of any need to downsize its generics portfolio. Defendants' materially false and misleading statements are set forth in full below, along with a summary of the material facts that Defendants withheld from the public that rendered their statements materially false and misleading.

A. Defendants' False And Misleading Statements Concerning Quality Assurance And Mylan's Attempts To Comply With CGMP And Data Integrity Standards

1. Defendants' False And Misleading Statements Published On The Mylan Website Throughout The Class Period

253. Throughout the Class Period, Defendants made public statements on Mylan's website touting the Company's rigorous product quality standards. Each of these statements were materially false and misleading because, as discussed above, Mylan's facilities, including its flagship Morgantown facility, were rife with serious, repeat CGMP and data integrity violations, including widespread efforts to evade mandatory product quality testing and standards by "testing into compliance." Therefore, as the FDA warned Mylan no later than 2016, the Company's "[l]aboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity," and "[t]here is a failure to thoroughly review any unexplained discrepancy whether or not the batch has already been distributed," among other serious CGMP deficiencies, as discussed above. Indeed, as discussed above, Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown.

254. Throughout the Class Period, on a webpage entitled "Quality," Defendants stated:

> Mylan applies one global quality standard across our facilities, and across our product line . . . regardless of market. At Mylan, whether it's a medication for millions or for a handful of people our priorities are to meet or exceed industry standards. Because there's nothing generic about our standards. Our internal teams conduct reviews of all products, start to finish. No matter where in the world they are made. In fact, we championed a law that empowers the FDA to biennially inspect all manufacturing facilities around the world that supply the U.S. market.

(ellipses in original).

255. Defendants' statements were materially false and misleading when made. It was misleading for Defendants to tout Mylan's quality assurance processes and its rigorous product

quality standards, and to state that Mylan's "internal teams conduct reviews of all products, start to finish" and the Company "uses advanced testing and monitoring systems to assure product adheres to testing acceptance criteria" when Mylan's facilities were rife with serious CGMP and data integrity violations, including widespread "testing into compliance." Further, far from "conduct[ing] reviews of all products, start to finish," Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown. Moreover, Mylan failed to investigate known product quality deficiencies, OOS results, and anomalies, and systematically bypassed testing and monitoring systems by, among other things, falsifying root cause reports, crashing computer systems, and altering drug sample sets as discussed above. Instead, as discussed above, Mylan re-tested drugs and equipment until passing results were achieved, or failed to open investigations at all, in violation of CGMP and data integrity standards.

256. Throughout the Class Period, Defendants made public statements on Mylan's website touting the Company's "One Global Quality" standard, the Company's commitment to "meet or exceed industry standards, and its "ongoing reviews to ensure quality and integrity of products, start to finish." On a webpage entitled "How We Make Generic Medicines At Mylan," Defendants stated:

> *One Global Quality Standard*. Whether it's a medication for millions or for a handful of people, our priorities are to meet or exceed industry standards. Our own teams conduct ongoing reviews to ensure quality and integrity of products, start to finish, and to continually improve for optimal quality and consistency.

257. Defendants' statements were materially false and misleading when made. In truth, as detailed above, Mylan's facilities, including Morgantown, were rife with serious, repeat CGMP and data integrity violations, including widespread "testing into compliance." Far from conducting "ongoing reviews to ensure quality and integrity of products, start to finish," Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at

Morgantown. Moreover, Mylan failed to investigate known product quality deficiencies, OOS results, and anomalies, and systematically bypassed quality monitoring systems by, among other things, falsifying root cause reports, crashing computer systems, and altering drug sample sets as discussed above. Instead, as discussed above, Mylan re-tested drugs and equipment until passing results were achieved, or failed to open investigations at all, in violation of CGMP and data integrity standards.

258. Throughout the Class Period, Defendants made public statements on Mylan's website that the Company used "advanced testing and monitoring systems to assure" compliance with regulatory and industry standards. On a webpage entitled "How We Make Generic Medicines At Mylan," Defendants stated:

> Mylan uses advanced testing and monitoring systems to assure product adheres to testing acceptance criteria that are in alignment with requirements established by standard-setting organizations around the world.

259. Defendants' statements were materially false and misleading when made. In truth, as detailed above, Mylan's facilities, including Morgantown, were rife with serious, repeat CGMP and data integrity violations, including widespread "testing into compliance." Contrary to Defendants' statement that Mylan "uses advanced testing and monitoring systems to assure product adheres to testing acceptance criteria," Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown. Moreover, Mylan failed to investigate known product quality deficiencies, OOS results, and anomalies, and systematically bypassed "testing and monitoring systems" by, among other things, falsifying root cause reports, crashing computer systems, and altering drug sample sets as discussed above. Instead, as discussed above, Mylan re-tested drugs and equipment until passing results were achieved, or failed to open investigations at all, in violation of CGMP and data integrity standards.

260. Throughout the Class Period, Defendants made public statements on Mylan's website touting the Company's "advanced" product quality monitoring systems, which Defendants stated exceeded CGMP requirements and were used to "reject" and "remove" OOS products. On a webpage entitled "How We Make Generic Medicines At Mylan," Defendants stated:

> *Advanced Monitoring Systems*. Although not required, Mylan utilizes state-of-the-art monitoring systems that can automatically evaluate and reject a product that does not meet specifications. This advanced technology is used to automatically remove a defective product from production or packaging lines.

261. Defendants' statements were materially false and misleading when made. In truth, as detailed above, Mylan's facilities, including Morgantown, were rife with serious, repeat CGMP and data integrity violations, including widespread "testing into compliance." Far from actually "us[ing]" its monitoring systems "to automatically remove a defective product from production or packaging lines," Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown. Moreover, Mylan failed to investigate known product quality deficiencies, OOS results, and anomalies, and systematically bypassed its "state-of-the-art monitoring systems" by, among other things, falsifying root cause reports, crashing computer systems, and altering drug sample sets as discussed above. Instead, as discussed above, Mylan re-tested drugs and equipment until passing results were achieved, or failed to open investigations at all, in violation of CGMP and data integrity standards.

262. Throughout the Class Period, Defendants made public statements on Mylan's website that Mylan performed product quality testing to ensure the Company had "proof of purity and potency" before drugs were marketed to the public. On a webpage entitled "How We Make Generic Medicines At Mylan," Defendants stated:

> *Proof of Purity and Potency*. Mylan assures product potency, purity and drug release through expiration date by testing the stability of our products at specific intervals."

263. Defendants' statements were materially false and misleading when made. In truth, as detailed above, Mylan's facilities, including Morgantown, were rife with serious, repeat CGMP and data integrity violations, including widespread "testing into compliance." In fact, the FDA specifically warned Mylan no later than 2016, the Company's "[l]aboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity," and "[t]here is a failure to thoroughly review any unexplained discrepancy whether or not the batch has already been distributed." Further, in the 2016 Form 483, the FDA specifically warned Mylan that its stability testing in connection with numerous drugs and drug products was "conducted using non-validated and non-verified analytical test methods" and cited numerous instances of inadequate investigation into failed stability results. Likewise, former Mylan employees reported widespread testing into compliance in connection with stability testing. For instance, as Eban reported, a former Mylan chemist stated that when drugs failed stability testing, "[y]ou play with the parameters so impurities don't show up." Moreover, as discussed above, Mylan failed to perform even nominal quality testing, including stability testing, on the vast majority of the drugs manufactured at Morgantown.

264. Throughout the Class Period, Defendants made public statements on Mylan's website that Mylan "used an established testing and verification process to" test the quality of its pharmaceutical ingredients. On a webpage entitled "How We Make Generic Medicines At Mylan," Defendants stated:

> *Protection Against Defects*. Quality begins at step one. Mylan uses an established testing and verification process to ensure the suitability of active ingredients used in our medicines.

265. Defendants' statements were materially false and misleading when made. In truth, as detailed above, Mylan's facilities, including Morgantown, were rife with serious, repeat CGMP

and data integrity violations, including widespread "testing into compliance." Indeed, in its 2016 Form 483, the FDA specifically warned Mylan that its stability testing in connection with APIs were "conducted using non-validated and non-verified analytical test methods." Moreover, as discussed above, Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown.

2. Defendants' False And Misleading Statements Made In SEC Filings And On Investor Conference Calls

266. In addition to the statements on Mylan's website, during the Class Period, Mylan and the Officer Defendants made numerous further statements in filings with the SEC and on calls with investors and securities analysts concerning Mylan's purportedly "stringent" quality standards. Defendants' statements, along with a summary of the facts rendering them false and misleading, are set forth chronologically below.

267. In an Annual Report filed with the SEC on Form 10-K on February 16, 2016, Defendants stated:

> Our global manufacturing platform is an important component of our business model . . . . with significant sites in Morgantown, West Virginia . . . . We believe that all of our facilities are in good operating condition, the machinery and equipment are well-maintained, the facilities are suitable for their intended purposes and they have capacities adequate for the current operations.

268. Defendants' statements were materially false and misleading when made. It was misleading for Defendants to state that Mylan's "facilities," including its "significant" Morgantown site, "are in good operating condition, the machinery and equipment are well-maintained," and that "the facilities are suitable for their intended purposes," when, in truth, Mylan's facilities, including Morgantown, were rife with serious, repeat CGMP and data integrity violations. Far from being "well-maintained" and "suitable for their intended purposes," both the FDA and Mylan's own Former Employees reported that Mylan manipulated testing of

manufacturing and packaging equipment by "testing into compliance," falsifying reports, and failing to perform required analyses in the first instance. Moreover, as discussed above, Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown. Further, it was misleading for Defendants to state that Mylan's facilities "have capacities adequate for the current operations," when, as Former Employees reported and Mylan privately admitted, the Company's widespread CGMP failures were a function of the enormous volume of drugs Mylan pushed through its facilities.

269. Additionally, in Mylan's SEC-mandated "Risk Disclosures" in the Form 10-K the Company filed on February 16, 2016, Defendants gave a misleadingly incomplete picture of Mylan's CGMP compliance and product quality risk: Defendants stated only that "there is no guarantee" Mylan's compliance programs and policies "will meet regulatory agency standards in the future or will prevent instances of non-compliance with applicable laws and regulations." Moreover, Defendants stated only that Mylan "may receive" notices of CGMP violations from regulators.

270. Defendants statements in Mylan's SEC-mandated "Risk Disclosures" were materially false and misleading when made. It was misleading for Defendants to state only that Mylan may not "meet regulatory agency standards in the future" and that Mylan "may receive" notices of CGMP violations from regulators, when Mylan's facilities, including its flagship Morgantown facility, were presently rife with serious, repeat CGMP and data integrity violations.

271. On June 7, 2016, Defendant Bresch attended the Goldman Sachs Global Healthcare Conference on behalf on Mylan. At that conference, an analyst asked Defendant Bresch about "top-line growth opportunities for Mylan over the next several years in a world where exclusive first-to-file opportunities are becoming more rare and the patent cliff for solid [dose medicine] is

waning? . . . How do you grow?" In response, Defendant Bresch touted Mylan's "operational excellence" as providing Mylan with a key competitive advantage. Defendant Bresch stated, "So, for a company like Mylan, who has prided itself on our operational excellence and making almost 80% of everything we sell, controlling that global supply chain, that brings a real point of leverage and to the business of our ability to do that."

272. Defendants' statements were materially false and misleading when made. It was misleading for Defendant Bresch to tout Mylan's "operational excellence," while failing to disclose that Mylan's facilities, including its flagship Morgantown facility, were rife with serious, repeat CGMP and data integrity violations, including widespread "testing into compliance." Mylan also failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown. Moreover, Mylan failed to investigate known product quality deficiencies, OOS results, and anomalies, and systematically bypassed testing and monitoring systems by, among other things, falsifying root cause reports, crashing computer systems, and altering drug sample sets as discussed above. Instead, Mylan re-tested drugs and equipment until passing results were achieved, or failed to open investigations at all, in violation of CGMP and data integrity standards.

273. In an Annual Report filed with the SEC on Form 10-K on March 1, 2017, Defendants repeated the statement, set forth in ¶267 above, concerning Mylan's purported belief that "all of our facilities are in good operating condition, the machinery and equipment are well-maintained, the facilities are suitable for their intended purposes and they have capacities adequate for the current operations."

274. Defendants' statements were materially false and misleading when made. It was misleading for Defendants to state that Mylan's "facilities," including its "significant"

Morgantown site, "are in good operating condition, the machinery and equipment are well-maintained," and that "the facilities are suitable for their intended purposes," when, in truth, Mylan's facilities, including Morgantown, were rife with serious, repeat CGMP and data integrity violations. Far from being "well-maintained" and "suitable for their intended purposes," both the FDA and Mylan's own Former Employees reported that Mylan manipulated testing of manufacturing and packaging equipment by "testing into compliance," falsifying reports, and failing to perform required analyses in the first instance. Moreover, as discussed above, Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown. Further, it was misleading for Defendants to state that Mylan's facilities "have capacities adequate for the current operations," when, as Former Employees reported and Mylan privately admitted, the Company's widespread CGMP failures were a function of the enormous volume of drugs Mylan pushed through its facilities.

275. Additionally, Mylan's 2016 Form 10-K, filed on March 1, 2017, repeated the same misleadingly incomplete "risk disclosure" set forth at ¶269 above. That risk disclosure made no mention of the either the Nashik or Morgantown Forms 483 the FDA had already issued to the Company, and, instead, touted the Company's supposed resolution of much of a different warning letter. In that 2016 Form 10-K, Defendants added the following to the "risk disclosure" concerning a warning letter relating to an Indian facility Mylan had acquired from, Agila Specialties another drug company: "On September 12, 2016, the FDA notified us that, based on its evaluation, it appeared we had addressed the issues related to SFF."

276. These statements were materially false and misleading when made. It was misleading for Defendants to state only that Mylan may not "meet regulatory agency standards in the future" and that Mylan "may receive" notices of CGMP violations from regulators, when

Mylan's facilities, including its flagship Morgantown facility, were presently rife with serious, repeat CGMP and data integrity violations and Mylan had already privately received multiple warnings from regulators that Morgantown's quality control processes were dangerously deficient and failed to meet regulatory standards. It was additionally misleading for Defendants to tout the Company's supposed resolution of much of the Agila warning letter in the "risk disclosure" Mylan included in its 2016 Form 10-K, while failing to disclose that the Company had been issued two Forms 483, including in connection with the Morgantown facility, citing serious, widespread CGMP and data integrity issues.

a) Defendants' Statements Following The Nashik Warning Letter And 2016 Form 483

277. On April 11, 2017, Mylan issued a statement to news outlets in response to the publication of the Nashik warning letter. Mylan told news media, including *Investor's Business Daily*:

> As FDA standards for our industry continue to evolve, we are dedicated to continually enhancing our systems and processes with a deliberate, thorough approach to assure sustainable quality across our entire network of facilities . . . . The Nashik, India, facility is just one of Mylan's 50 manufacturing sites across the globe with 24 focused on oral solid doses. Production is ongoing and Mylan doesn't expect any supply issues related to products being manufactured at the India site.

278. Defendants' statements were materially false and misleading when made. It was misleading for Mylan to state that it was "dedicated to continually enhancing our systems and processes, with a deliberate and thorough approach to ensure sustainable quality across our entire network of facilities," to blame "evolv[ing]" regulatory standards for the issues at the Nashik facility, and to state that Nashik's CGMP deficiencies were an anomaly and that the "facility is just one of Mylan's 50 manufacturing sites." Defendants failed to disclose, among other things, that (i) the FDA had already issued a Form 483 to Mylan identifying the same serious CGMP and data

integrity violations cited in the Nashik warning letter, including widespread efforts to evade mandatory product quality testing and standards by "testing into compliance," at the Company's flagship Morgantown facility; (ii) that FDA officials told Defendant Malik directly that Morgantown's failures were "egregious" and raised serious questions about the integrity of the Company's products; (iii) that Mylan had been forced to recall numerous drugs manufactured at Morgantown as a result of the Company's dangerous CGMP failures; and (iv) that Mylan would have to implement costly remedial measures in order to address the systemic violations at Morgantown.

279. On May 10, 2017, Mylan held its first quarter earnings call, attended by Defendants Bresch, Malik, Parks, and others. On that call, Defendant Malik reassured investors about the Nashik warning letter and Mylan's facilities generally, stating:

> With regards to our operating platform, Mylan has always had a deep and unwavering commitment to quality everywhere we operate. FDA standards for our industry continue to evolve, and this continues to raise the bar for every player in our industry, which is something we very much welcome. For Mylan's part, we are dedicated to continually enhancing our systems and processes, with a deliberate and thorough approach to ensure sustainable quality across our entire network of facilities, working closely with FDA to resolve any issues that come our way. As you are aware, we recently received a warning letter at our Nashik site in India. We are working closely with the FDA to respond to and address the issues raised in the letter as comprehensively and expeditiously as possible.
>
> At the same time, we have successfully completed remediation efforts at the 3 sites acquired from Agila that were under FDA warning letters. The warning letters have been lifted at both SFF and SPD sites and we are pleased with our progress at OTL site, which also was very recently inspected by FDA.
>
> I note that during the quarter, we [had] shifting inspections by various global regulators across our 50 facilities.

280. Defendants' statements were materially false and misleading when made. It was misleading for Defendant Malik to tout Mylan's "deep and unwavering commitment to quality," to state that Mylan was "dedicated to continually enhancing our systems and processes, with a

deliberate and thorough approach to ensure sustainable quality across our entire network of facilities," to blame "evolv[ing]" regulatory standards for the issues at the Nashik facility, to state that Nashik's CGMP deficiencies were an anomaly, and to highlight supposedly positive inspections at all of Mylan's other facilities. Defendants failed to disclose, among other things, that (i) the FDA had already issued a Form 483 to Mylan identifying the same serious CGMP and data integrity violations cited in the Nashik warning letter, including widespread efforts to evade mandatory product quality testing and standards by "testing into compliance," at the Company's flagship Morgantown facility; (ii) that FDA officials told Defendant Malik directly that Morgantown's failures were "egregious" and raised serious questions about the integrity of the Company's products; (iii) that Mylan had been forced to recall numerous drugs manufactured at Morgantown as a result of the Company's dangerous CGMP failures; and (iv) that Mylan would have to implement costly remedial measures in order to address the systemic violations at Morgantown.

281. On May 23, 2017, Mylan filed its proxy statement with the SEC on Schedule 14A in connection with the Company's upcoming annual shareholder meeting, in which the Company touted Mylan's "high quality manufacturing platform":

> Relentless execution of Mylan's strategy over the last decade has produced a highly differentiated global company capable of making high quality medicines available to everyone who needs them. Among our many strengths . . . . **Powerful, high quality manufacturing platform:** Our 50 plants around the world manufacture tens of billions of doses of medicine annually, and each site adheres to stringent quality standards, regardless of location.

(bold emphasis in original).

282. Defendants' statements were materially false and misleading when made. It was misleading for Defendants to tout Mylan's quality assurance processes and its "high quality manufacturing platform" as key "strengths" of the Company, and to state that "each" of Mylan's

sites "adheres to stringent quality standards, regardless of location," while failing to disclose that (i) Mylan's facilities, including Morgantown, were rife with serious, repeat CGMP and data integrity violations, including widespread efforts to evade mandatory product quality testing and standards by "testing into compliance"; (ii) that Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown; (iii) that the FDA had issued a lengthy Form 483 to Mylan citing the egregious and widespread CGMP violations at the Morgantown facility; and (iv) that Mylan had been forced to recall numerous drugs manufactured at Morgantown as a result of the Company's dangerous CGMP failures.

283. On May 22, 2017, Mylan issued its annual Environmental, Social, and Governance Report ("ESG") to shareholders. The report quoted Defendant Bresch as stating that Mylan has "an extensive portfolio of more than 7,500 marketed products . . . . We are able to manufacture tens of billions of doses of medicine annually, all to stringent quality standards."

284. Mylan's 2017 ESG report further stated,

> From a manufacturing and supply chain perspective—typically the most scrutinized area of any pharmaceutical company—Mylan has invested significant resources to ensure quality throughout our value chain. Each of its steps is wrapped in a series of reviews designed to meet or exceed the many regulatory and compliance standards enforced by the dozens of health authorities around the globe that regularly inspect us. The result is an integrated global network capable of providing pharmaceuticals that patients the world over can trust.

285. Defendants' statements were materially false and misleading when made. It was misleading for Defendants to tout Mylan's "significant" investment in quality assurance processes, to state that Mylan had implemented a redundant "series of [quality] reviews" throughout its manufacturing and distribution process, and to state that each of those steps were "designed to meet or exceed the many regulatory and compliance standards" to which Mylan was subject. In truth, far from implementing "a series" of quality reviews at "each step" in the supply chain, Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at

Morgantown, failed to investigate known product quality deficiencies, and systematically bypassed the "series of reviews" Defendants touted. As described above, Mylan evaded CGMP and data integrity regulations by, among other things, falsifying root cause reports, crashing computer systems, altering drug sample sets, and re-testing drugs and equipment until passing results were achieved. Moreover, far from being "designed to meet or exceed" regulatory standards, Mylan's facilities, including Morgantown, were rife with serious, repeat CGMP and data integrity violations, including widespread efforts to evade mandatory product quality testing and standards by "testing into compliance." Indeed, Defendants failed to disclose that the FDA had issued a lengthy Form 483 to Mylan citing the egregious and widespread CGMP violations at the Morgantown facility and that Mylan had been forced to recall numerous drugs manufactured at Morgantown as a result of the Company's dangerous CGMP failures.

286. On Mylan's August 9, 2017 earnings call, Defendant Malik again reassured investors about the Nashik warning letter, stating:

> With regards to our operating platform, we are in the constructive dialogue with the FDA regarding the warning letter that our Nashik site in India received earlier this year. We are working closely with the agency to comprehensively resolve their 2 observations as expeditiously as possible. The site remains in good standing with other global regulatory entities, including WHO and MHRA.
>
> We are pleased to have had the warning letter from Agila Oncology site lifted during this quarter, joining SFF and SPD in being cleared by FDA.

287. Defendants' statements were materially false and misleading when made. In purporting to update investors on Mylan's "operating platform," it was misleading for Defendant Malik, to state that Mylan was in "constructive dialogue with the FDA" concerning the Nashik warning letter and tout its supposed remediation of CGMP deficiencies at the site Mylan acquired from Agila, while failing to disclose that (i) the FDA had already issued a Form 483 to Mylan identifying the same serious CGMP and data integrity violations cited in the Nashik warning letter,

including widespread testing into compliance, at the Company's flagship Morgantown facility; (ii) that FDA officials told Defendant Malik directly that Morgantown's failures were "egregious" and raised serious questions about the integrity of the Company's products; (iii) that Mylan had been forced to recall numerous drugs manufactured at Morgantown as a result of the Company's dangerous CGMP failures; and (iv) that Mylan would have to implement costly remedial measures in order to address the systemic violations at Morgantown.

288. In an Annual Report filed with the SEC on Form 10-K on March 1, 2018, Defendants repeated the statement set forth in ¶267 above. These statements were materially false and misleading when made. It was misleading for Defendants to state that Mylan's "facilities," including its "significant" Morgantown site, "are in good operating condition, the machinery and equipment are well-maintained," and that "the facilities are suitable for their intended purposes," when, in truth, Mylan's facilities, including its flagship Morgantown facility, were rife with serious, repeat CGMP and data integrity violations, including widespread efforts to evade mandatory product quality testing and standards by "testing into compliance." Indeed, as both the FDA and Mylan's own Former Employees reported, Mylan manipulated testing of manufacturing and packaging equipment by "testing into compliance," falsifying reports, and failing to perform required analyses in the first instance. Moreover, as discussed above, Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown. Further, it was misleading for Defendants to state that Mylan's facilities "have capacities adequate for the current operations," when, as Former Employees reported and Mylan privately admitted, the Company's widespread CGMP failures were a function of the enormous volume of drugs Mylan pushed through its facilities.

289. Additionally, in Mylan's SEC-mandated "Risk Disclosures" in the Form 10-K the Company filed on March 1, 2018, Defendants repeated the same misleadingly incomplete picture of Mylan's CGMP compliance and product quality risk set forth at ¶269 above. These statements were materially false and misleading when made. It was misleading for Defendants to state only that Mylan may not "meet regulatory agency standards in the future" and that Mylan "may receive" notices of CGMP violations from regulators, when Mylan's facilities, including its flagship Morgantown facility, were presently rife with serious, repeat CGMP and data integrity violations. Moreover, at the time Defendants issued this Risk Disclosure, Mylan had already privately received multiple warnings from regulators that Morgantown's quality control processes were dangerously deficient and failed to meet regulatory standards.

b) Defendants' Statements Following The March 2018 Surprise Inspection Of Morgantown

290. On April 20, 2018, Mylan issued a statement to reporters announcing that it was laying off 15% of the employees at Morgantown. Mylan stated:

> As the industry has changed and regulatory expectations have continued to evolve, we've realized that our Morgantown plant needed to be rightsized to be less complex. The right-sizing is consistent with discussions we are having with the U.S. Food and Drug Administration and is necessary in order to position the site as best we can for continued operations.

291. Defendants' statements were materially false and misleading when made. It was misleading for Defendants to state that Mylan was "right-sizing" the workforce at the Morgantown plant simply because management "realized" the facility needed "to be less complex," while failing to disclose that, in reality, the "right-sizing" was driven by the FDA's issuance—for the second time in two years—of a Form 483 citing Morgantown's serious, repeat CGMP and data integrity violations. As a result, the Company had halted production at the facility, significantly reduced the "broad" portfolio of generic drugs Defendants had touted throughout the Class Period,

was already in the process of recalling numerous drugs manufactured at Morgantown, and was forced to implement expensive remedial measures greatly increasing operating costs.

292. On May 10, 2018, Mylan issued its annual ESG report to shareholders. As the 2018 ESG report explains, its "[c]ontent is based on relevant ESG considerations and addresses topics in which our stakeholders have expressed interest." In a section of the 2018 report entitled "Maintaining Quality In Everything We Do," Defendants touted Mylan's quality control processes and manufacturing standards, including Mylan's Quality Council's effective oversight of these critical functions. Defendants stated,

> For us, quality begins with product development, as we work to ensure an acceptable safety and efficacy profile for every drug we hope to market, and it extends through every step of the production process, from making or sourcing raw materials to producing finished dosage forms . . . . Mylan has global systems and processes in place to provide our people with the foundation and tools needed to maintain an effective quality management system . . . . Our Quality Council program provides management with clear, quantitative data, including that of key performance indicators. It also tracks and analyzes quality trends, reviews inspection results and identifies potential areas for employee training.
>
> * * *
>
> In addition, we have an extensive, formal internal-audit program to help monitor activity at our facilities, as well as that of our suppliers and other partners.

293. Likewise, in a section of that same 2018 ESG report entitled "Ensuring Quality and Product Safety," Mylan stated that it performed 42 "quality and GMP audits at [its] own facilities."

294. Defendants' statements were materially false and misleading when made. It was materially misleading for Defendants to tout Mylan's quality assurance processes, its rigorous product quality standards, the oversight provided by its "Quality Council program," and the numerous "quality and GMP audits" conducted pursuant to the Company's "extensive, formal internal-audit program." In truth, Mylan's facilities, including its flagship Morgantown facility, were rife with serious, repeat CGMP and data integrity violations, including widespread efforts to

evade mandatory product quality testing and standards by "testing into compliance." Moreover, Defendants' statements failed to disclose that the FDA had already issued Mylan two Forms 483 citing serious and pervasive CGMP violations at Morgantown in as many years. Contrary to Defendants' statements touting Mylan's "Quality Council program," the FDA specifically found that the Quality Council had failed to appropriately apply and enforce CGMP standards consistent with both FDA regulations and Mylan's own operating requirements, citing "numerous instances of a lack of appropriate oversight." Further, Defendants failed to disclose that, as a result of the FDA's inspections, the Company had halted production at the Morgantown facility, significantly reduced the "broad" portfolio of generic drugs Defendants had touted throughout the Class Period, was already in the process of recalling numerous drugs manufactured at Morgantown, and was forced to implement expensive remedial measures greatly increasing operating costs.

295. On May 10, 2018, Mylan filed its first quarter Form 10-Q, which incorporated by reference Mylan's misleadingly incomplete SEC-mandated "Risk Disclosures" set forth at ¶269 above. Mylan's May 10, 2018 Form 10-Q stated, "There have been no material changes in the Company's risk factors from those disclosed in Mylan's Annual Report on Form 10-K for the year ended December 31, 2017, as amended." Mylan's risk disclosure made no mention of either the 2016 or 2018 Morgantown Forms 483 the FDA had already issued to the Company.

296. These statements were materially false and misleading when made. It was misleading for Defendants to state only that Mylan may not "meet regulatory agency standards in the future" and that Mylan "may receive" notices of CGMP violations from regulators, when Mylan's facilities, including its flagship Morgantown facility, were presently rife with serious, repeat CGMP and data integrity violations. Moreover, Defendants failed to disclose that Mylan had already privately received multiple warnings from regulators that Morgantown's quality

control processes were dangerously deficient and failed to meet regulatory standards. In fact, by this time, Mylan had already received two Form 483's in just two years citing egregious and widespread CGMP violations at the Morgantown facility, and, as a result, Mylan had halted all production at the facility, had dramatically reduced the Company's portfolio of generic drugs, had recalled numerous drugs manufactured at the Morgantown facility, and had been forced to begin implementing drastic remedial measures.

297. Shortly before market-close on June 27, 2018, *Bloomberg* issued a brief news alert reporting that the FDA had concluded a four-week inspection of the Morgantown facility in April 2018 and had issued a Form 483 citing multiple CGMP violations. Under pressure to respond and in an effort to spin the story to quell investor concern, Mylan issued a press release on June 28, 2018 that downplayed the Morgantown inspection and failed to disclose key, highly material facts to investors. The press release stated:

> Mylan is committed to maintaining the highest quality manufacturing standards at its facilities around the world. In support of this commitment, Mylan's plants are regularly inspected by health authorities to ensure compliance for the various markets we serve. The U.S. Food and Drug Administration (FDA) recently completed an inspection at Mylan's plant in Morgantown and made observations through a Form 483. The company has submitted a comprehensive response to the Agency and committed to a robust improvement plan.
>
> We remain confident in the quality, safety and efficacy of our drug products, including those in distribution, and we continue to manufacture and ship product from the site. Mylan will continue to maintain a close dialogue with the Agency and is fully committed to working with FDA to address its observations.

298. Defendants' statements were materially false and misleading when made. It was misleading for Defendants to tout Mylan's "commit[ment] to maintaining the highest quality manufacturing standards at its facilities around the world," to state that it remained "confident in the quality, safety and efficacy of our drug products, including those in distribution," and to claim that "we continue to manufacture and ship product from" Morgantown. In truth, the seriousness

and pervasiveness of the CGMP violations the FDA identified at Morgantown had already forced Mylan to (i) halt manufacturing at the facility; (ii) significantly reduce the Company's "broad" portfolio of generic drugs that Defendants touted throughout the Class Period; (iii) recall numerous drugs manufactured at Morgantown; and (iv) implement expensive remedial measures greatly increasing operating costs.

299. In a January 31, 2019 *Bloomberg* article, Defendants responded to allegations of CGMP and data integrity failures at Mylan's plants, including the practice of "testing into compliance." Defendants stated that Mylan manufactures all of its products at all of its facilities "under stringent processes, procedures and rigorous testing designed to ensure that they meet the highest standards for quality, safety and efficacy. Any explicit or implicit suggestion that Mylan employees circumvented data and quality systems that jeopardized the quality of the medications we manufacture—for time pressures or any other reason—is simply false."

300. Defendants' statements were materially false and misleading when made. It was misleading for Defendants to state that Mylan's manufacturing occurs "under stringent processes, procedures, and rigorous testing" and that the Company's protocols were "designed to ensure that they meet the highest standards for quality, safety and efficacy." In truth, and as FDA investigators had discovered, Mylan's facilities, including its flagship Morgantown facility, were rife with serious, repeat CGMP and data integrity violations, including widespread efforts to evade mandatory product quality testing and standards by "testing into compliance." Mylan failed to perform even nominal quality testing on the vast majority of the drugs manufactured at Morgantown. Moreover, Mylan failed to investigate known product quality deficiencies, OOS results, and anomalies, and systematically bypassed quality monitoring systems by, among other things, falsifying root cause reports, crashing computer systems, and altering drug sample sets as

discussed above. Instead, as discussed above, Mylan re-tested drugs and equipment until passing results were achieved, or failed to open investigations at all, in violation of CGMP and data integrity standards. The seriousness and pervasiveness of the CGMP violations the FDA identified at Morgantown had already forced Mylan to (i) halt manufacturing at the facility, (ii) significantly reduce the Company's "broad" portfolio of generic drugs that Defendants touted throughout the Class Period, (iii) recall numerous drugs manufactured at Morgantown, and (iv) implement expensive remedial measures greatly increasing operating costs.

B. Defendants' False And Misleading Statements Concerning Mylan's "Broad" Operating Capacity And Asserting That The Company Did Not Need To Downsize Its Generics Portfolio

301. Throughout the Class Period, Defendants Bresch and Parks (Mylan's CFO) consistently and misleadingly attributed Mylan's success in the face of generic price erosion to its broad manufacturing capacity, which allowed the Company to manufacture to reliably produce industry-leading volume of drugs "all to stringent quality standards." Defendants repeatedly told investors that Mylan's vast operating capacity gave the Company distinct competitive advantages in both retaining customers and taking advantage of market shortages. Each of these statements were materially misleading because they omitted to disclose that Mylan had met the volume demands of its customers only by abandoning CGMP standards at its flagship Morgantown facility. In fact, as investors learned at the end of the Class Period, Mylan's operating capacity was severely constrained, and the Company could not produce the same volume of product at the level of quality that the FDA requires and consumers demand. Defendants' statements on this topic, which are all misleading by the omission of these same material facts, are set forth below chronologically.

302. On May 10, 2016, Defendant Bresch attended the Bank of America Merrill Lynch Healthcare Conference on behalf of Mylan. At that conference, an analyst asked Defendant Bresch

what was allowing Mylan to weather generic price erosion better than "some of the other players." Defendant Bresch stated:

> Here in the United States, we have 400 products across every therapeutic category and have critical mass around many, many different dosage forms. It allows you to absorb that volatility. And then, not only do we have that many products, but, as I said, we manufacture 80% of what we sell. So, our ability to be nimble, to react to market opportunities, to react to customer disruption, when other players; that ability truly is not only allows you to manage through volatility, but it certainly then puts a different perspective of how you're leveraged with the customers. As our customers continue to consolidate, they need more product. Their reliance and needing for certainty has gone to an all-time high.
>
> * * *
>
> If you look, then, not only investing, but everything from complex products to the commodity products that you've got that full offering. On top of that, having the manufacturing operating platform that is allowing you to make what you're selling, vertically integrate, and have that global supply chain.

303. On June 7, 2016, Defendant Bresch attended the Goldman Sachs Global Healthcare Conference on behalf on Mylan. At that conference, an analyst asked Defendant Bresch how Mylan was combating price erosion in the generics market. In response, Defendant Bresch stated that Mylan's operating capacity gave the Company an advantage in attracting customers, especially as other drug companies failed FDA inspections. Defendant Bresch stated:

> It's always been a volume-driven business, always . . . . [T]here's a much—more of a sense from our customer base that having a reliable global supply chain is important, that they don't want to have to turn customers away because of products—they're not able to get their hands on a product. So, if anything, we continue to see it to be a win-win . . . . But, let's also remember the inspections, the quality side of the house . . . . So, I think you're going to continue to see facilities, drug shortages, facilities shut down that aren't where they need to be to supply the US market.

304. On August 9, 2016, Mylan held its second quarter earnings call, attended by Defendants Bresch, Malik, Parks, and others. On that call, Defendant Bresch touted Mylan's "extensive manufacturing operations," stating, "In Mylan's case, we have spent the last decade differentiating, diversifying, and derisking by expanding through organic growth and strategic

acquisitions. As a result, we now have extensive manufacturing operations whose technologies range from API to oral solids, to injectables, transdermals, and respiratory expertise."

305. Likewise, on that same call, Defendant Bresch further stated:

> The need for a reliable supply is continuing to, I think, again, be a differentiator for Mylan and our ability to meet these global needs in a very reliable—as we've touted before, through sheer hard work that has been put together this last decade is a supply chain that we believe is second to none. And, I think you see some value, continued value, being placed on that by our customers . . . . So I think, it continues to shift towards being a not only a differentiator for us, but a real value driver and growth driver for us, which is why we have the confidence around the stability in the market.

306. On Mylan's November 9, 2016 earnings call, an analyst asked how Mylan was reporting stable revenues when "many of your peers, as you know, this week, have described a worsening pricing environment, driven by consolidation of buyers." Defendant Bresch responded that Mylan's "capacity and capability of supplying" demand gave Mylan a significant competitive advantage:

> [T]hat mix, that portfolio, and our capacity and capability of supplying the demands that's needed out there. It's what has allowed us to continue to compete in a market, that I would say has always been competitive.

307. On January 11, 2017, Defendants Bresch, Malik, and Parks attended the J.P. Morgan Healthcare Conference on behalf of Mylan. At that conference, an analyst asked Defendants to discuss Mylan's "position in the market, how you are thinking about pricing and just how do you respond to that skepticism around the sustainability of the price dynamic?" In response, Defendant Bresch again cited Mylan's operating capacity, specifically highlighting its U.S. production, which was driven by the Morgantown facility. Defendant Bresch stated:

> I truly think that it goes back to that our vision and strategy of having this, not just a broad product portfolio but strategically thinking about, if you think about here in the US, everything from the institutional market, the generic market, the prescription market, the OTC market, and if you think about the consolidation that our customers have had, so you look at the channel and the supply chain and to have [the] ability to be that reliable supplier with the capacity to do the kind of the

> volumes that need to be done across these products, because if I look back last year Mylan was one in every 13 scripts and the United States was filled with the Mylan medicine. That's 21 billion doses. That's more than Pfizer, Merck, J&J, Sanofi, Astra, all combined. So there aren't many that have truly built an integrated global supply chain that can deliver the kind of volume reliably at the same time continuing to invest and bring complex products to the market.

308. On May 22, 2017, Defendant Parks attended the UBS Global Healthcare Conference on behalf of Mylan. At that conference, an analyst asked Parks whether "you feel like the scale really does matter in negotiating with the consortium [of customers]" and operating capacity would allow Mylan to mitigate price erosion. Defendant Parks answered in the affirmative, stating:

> [A]s [customers] get bigger, they want to think about things like availability, service levels, the ability to provide all the different products they need without having to go to 15, 20 different places necessarily. So it doesn't necessarily take pricing off the table. It actually adds more value to other parts of the discussion when you have scale as well in those types of arrangements.

309. At that same conference, an analyst asked Defendant Parks whether Mylan's operational capacity was constrained and the Company "need[ed to acquire] anything else." Parks stated, "So we've been clear that we say we don't need any large infrastructure plays. We have a lot of the scale that we need."

310. On August 9, 2017, Mylan held its second quarter earnings call, attended by Defendants Bresch, Malik, and Parks. On that call, a J.P. Morgan analyst asked Defendant Bresch, "should we be thinking about a high single-digit price erosion as something that's likely to continue for the foreseeable future?" Defendant Bresch responded:

> I would say that the consolidation, obviously, you continue to see, I think, we're down really now to about 3 buying consortiums here in the United States . . . . So I think that our ability to partner and leverage our global scale with these global buying consortiums, that we are best positioned to take our entire product portfolio across the globe and be one of the best partners out there.

311. On November 6, 2017, Mylan held its third quarter earnings call, attended by Defendants Bresch, Malik, and Parks. On that call, Defendants were asked whether Mylan would spend money to acquire additional assets. Defendant Bresch replied that Mylan had all the operational capacity it needed. She stated, "We have been pretty staunch and since the Meda acquisition that we really had the assets that we needed to leverage this global commercial platform and have that infrastructure in place."

312. On January 9, 2018, Defendants Malik, Bresch, and Parks attended the J.P. Morgan Healthcare Conference on behalf of Mylan. At that conference, Defendants Bresch and Malik both touted the competitive advantages Mylan's broad generics portfolio gave the Company and told investors that Mylan did not need to cede this advantage by reducing, or "rationalizing," that portfolio. In response to an analyst question about Mylan's competitors "rationalizing portfolios," Defendant Malik stated:

> [W]e have already seen some pressure around drug shortages, around the commodities because everybody is trying to look at where you make money, where you don't make money. And the first one which stand out over there is those loss-making products. And we have a broad portfolio, we have a broad offering. We have a vertically integrated platform, which is tuned up to deliver to this market.

313. Likewise, at the January 9, 2018 conference, an analyst asked Defendants about the impact of price erosion on Mylan's business. Again, Defendant Bresch emphasized that Mylan's vast operating capacity and broad portfolio were allowing the Company to mitigate the impact of erosion better than its competitors. Defendant Bresch stated,

> [T]he larger [customers have] become, the larger their needs have become. And I don't think there's very many players out there today that can actually fulfill the breadth of the product and the reliability that they need. And secondly, I think it's—you can't look at all companies created equally that they're negotiating with, because again, I think, where Mylan has differentiated itself is, one, having that broad base, that portfolio, the capacity to truly meet the supply that's needed and the investing in these complex products. And all of that gives us a seat at the table perhaps a bit differently than our peers.

314. Similarly, at that same conference, an analyst asked whether Mylan needed to reduce its generics portfolio in order to limit its exposure "loss-making products." Defendant Bresch, specifically referencing the Morgantown facility, responded, and Defendant Malik agreed:

> [W]e're running facilities that are making 15 billion tablets and capsules in a year . . . . And what you could be making less money on one day, you could be making more on the next, given the dynamics in the supply chain. So for us, as others are having financial constraints or having to make perhaps short-term decisions because they have to, I think we have found ourselves in a position to really take into consideration again that long-term view.

315. Later, at that same investor conference, in response to another analyst question about how Mylan would resist price erosion "if nobody cuts capacity." Defendant Bresch responded:

> I think there are players dropping out of the market. I think we've seen it . . . . So what my point was, as companies are rationalizing, we're able to kind of be patient and make sure we're making that right longer-term decision versus a very knee-jerk reaction to what's happening in the market at the moment. As you know, that can change very quickly.
>
> * * *
>
> So as other companies are forced to rationalize or look at things, absolutely we're looking at that as an opportunity. And from the facilities we have here in the U.S., Europe and around the world to be able to strategically be able to absorb those different volumes is what we've really been set up to do.

316. On March 5, 2018, Defendant Parks attended the Raymond James Institutional Investor Conference, on behalf of Mylan. At that conference, an analyst asked Defendant Parks, to "talk about any potential product portfolio rationalization" in light of the "large-scale rationalization" by "a lot of the major players." Defendant Parks responded:

> [W]e have not talked about rationalization at all in the U.S. space. We've heard some of our peers and competitors talk about rationalization in the U.S. generic space . . . . And I think some of these larger customers value the fact that you can bring to them more today than 5 years ago the ability to supply them with a broader range of products because they, in turn, have a commitment to their own customers to meet time and delivery and availability of product.

317. On March 14, 2018, Defendant Bresch attended the Barclays Global Healthcare Conference on behalf of Mylan. In response to an analyst question, Defendant Bresch touted Mylan's "operational excellence" and "ability to manufacture high-quality, high-volume products" as key competitive advantages that would allow Mylan to capitalize on supply shortages:

> So I think the credibility of our science, our portfolio, our ability, our operational excellence, the ability to manufacture high-quality, high-volume products around the globe, I think has been a hallmark of Mylan. And our ability to be that reliable supplier in what has continued to be a consolidated marketplace . . . . And I think Teva and Sandoz are focused very differently right now, and we see opportunity in that. Because I think there's opportunity for us to pick up supply.

318. In sum, each of Defendants' above statements was materially false and misleading when made. It was misleading for Defendants to tout Mylan's vast operational capacity and the competitive advantage it was giving Mylan and state that the Company would not have to "rationalize" its portfolio. In truth, and as the Company privately admitted, Mylan's manufacturing capacity at its flagship Morgantown facility—the bulwark of its U.S. generics business—was severely constrained. The overwhelming output demands Defendants placed on the plant rendered it impossible for Mylan to comply with its regulatory obligations and to perform the rigorous quality testing it assured investors it was performing on "all products, start to finish."

319. On June 13, 2018, Defendant Bresch attended the Goldman Sachs Global Healthcare Conference on behalf of Mylan. An analyst asked Defendant Bresch, "[H]ow do you feel about where we are with just the whole U.S. generic drug landscape?" Defendant Bresch responded:

> I couldn't be more excited about not only our portfolio—our current portfolio before even getting to the pipeline about the reliability, our ability to supply, our ability to be patient and be able to take advantage of the opportunities in the marketplace because of some other companies being forced to take certain actions . . . . [O]ur ability to supply has really allowed us to continue to step up and be able to take advantage of that in the marketplace.

320. Defendants' statements, made after the Company had started significant undisclosed remediation efforts to address the 2018 Form 483, were materially false and misleading when made. It was misleading for Defendant Bresch to tout Mylan's vast operational capacity, "our ability to supply, our ability to be patient and be able to take advantage of the opportunities in the marketplace" as key competitive advantages and to state that Mylan's "ability to supply has really allowed us to continue to step up and be able to take advantage of that in the marketplace," while failing to disclose that Mylan had already been forced to halt production at the Morgantown facility, significantly reduce its generics portfolio, recall numerous drugs manufactured at Morgantown, and implement expensive remedial measures. Indeed, as the Company privately admitted, Mylan's manufacturing capacity at its flagship Morgantown facility—the bulwark of its U.S. generics business—was severely constrained. The overwhelming output demands Defendants placed on the plant rendered it impossible for Mylan to comply with its regulatory obligations and perform the rigorous quality testing it assured investors it was performing on "all products, start to finish."

C. Defendants' False And Misleading Statements Concerning The Impact On Mylan's Business Of The FDA's Regulatory Actions And The Company's Subsequent Remediation Efforts

321. On August 8, 2018, during Mylan's earnings call following its announcement that the 2018 Form 483 had forced them to undertake a remediation and restructuring program at Morgantown, Defendant Parks stated:

> [W]e believe that . . . effectively, the part of our business that we want to bring back, we're comfortable that, that remediation and restructuring is going to be completely effective for Morgantown. And therefore, our profitable business will come back into the portfolio and we've made some choices around certain products as we simplify and make the Morgantown facility less complex. So overall, this impact is temporary and we believe that our profitability levels are sustainable.

322. On this same call, Defendant Malik further falsely stated that the Morgantown restructuring "was not triggered just by this FDA inspection. It was part of . . . this year's plan actually to right size it. Because we have observed that it will be very difficult for us to manage this sort of complexity which Morgantown has, which 20 billion doses, with evolving FDA expectations."

323. On this same call, Defendant Bresch stated:

> [W]e are continuing to totally up that facility and doing it as quickly as we possibly can. So certainly, we are hopeful, I think as Rajiv said, that through 2018, that we will be seeing that continued turnaround and us continuing to be able to rebring volume back up to where we said we were bringing it back up to, which is obviously streamlined from where the facility has been historically. So kind of that rightsizing and remediation is all happening simultaneously.

324. Defendants' statements were false and misleading when made. It was misleading for Defendants to state that the Morgantown restructuring "was not triggered just by this FDA inspection," that the Morgantown "right-sizing" was simply as "part of . . . this year's plan," and that the remediation was driven by "evolving FDA expectations" while failing to disclose that the "right-sizing" was driven in significant part by the FDA's issuance—for the second time in two years—of a Form 483 citing Morgantown's serious, repeat CGMP and data integrity violations. It was also misleading for Defendants to claim that the impact of the remediation program on Mylan's business would be "temporary" and the Mylan's "profitability levels are sustainable," while failing to disclose that, in truth, Mylan's remediation entailed a severe and permanent reduction in the Morgantown's production levels and in the Company's generics portfolio. Moreover, Mylan's extensive remediation was not only causing severe reductions in production levels, but also significant increases in operating costs.

325. On November 5, 2018, Mylan held its earnings call for the third quarter of 2018 and further falsely minimized the news of the Morgantown restructuring and its dramatic impact

on Mylan's bottom line. Specifically, Defendant Bresch stated, "Let me start by celebrating the broad contribution, in fact, of our Morgantown facility's restructuring and remediation, which began in the second quarter of this year on our North American business as this may have been misunderstood by the investment community." Defendant Bresch continued, "These actions have led to a temporary disruption in supply of certain products for our customers and reduced volume in North America generic sales. However, the value related to the rationalized product is not proportionate to the reduced volumes of those commoditized products."

326. Defendants' statements were false and misleading when made. It was misleading for Defendants to claim that the impact of the Morgantown remediation program on Mylan's business would be a "temporary disruption" and "reduced volume in North America generic sales." Mylan's CGMP and data integrity violations at Morgantown were far more widespread and had a far greater impact on the Company's business than Defendants admitted. In truth, Mylan's remediation entailed a severe and permanent reduction in the Morgantown's production levels and in the Company's generics portfolio. Moreover, Mylan's extensive remediation was not only causing severe reductions in production levels, but also significant increases in operating costs.

327. Defendants' statements were materially false and misleading when made. It was misleading for Defendants to claim that the "negative financial impact [of the remediation program] on the business" was "largely behind us" when, these facts were continuing to significantly impact Mylan's business. Mylan's CGMP and data integrity violations at Morgantown were far more widespread and had a far greater impact on the Company's business than Defendants admitted. In truth, Mylan's remediation entailed a severe and permanent reduction in the Morgantown's production levels and in the Company's generics portfolio.

Moreover, Mylan's extensive remediation was not only causing severe reductions in production levels, but also significant increases in operating costs.

VIII. LOSS CAUSATION

328. During the Class Period, as detailed in this Complaint, Defendants made materially false and misleading statements and omissions, and engaged in a scheme to deceive the market. Defendants' scheme artificially inflated the price of Mylan stock and operated as a fraud and deceit on the Class. As a result of Defendants' materially false or misleading statements, omissions of material facts, and fraudulent course of conduct, Mylan's common stock traded at artificially inflated prices during the Class Period. Relying on the integrity of the market price for Mylan common stock and public information relating to Mylan, Lead Plaintiff and other Class members purchased or otherwise acquired Mylan common stock at prices that incorporated and reflected Defendants' misrepresentations and omissions of material fact alleged herein.

329. Later, when the relevant truth regarding Defendants' prior misrepresentations and omissions of material fact were disclosed to the market on June 28, 2018, August 8, 2018, February 26, 2019, and May 7, 2019, the price of Mylan's stock fell. As a result of their purchases of Mylan securities during the Class Period, Lead Plaintiff and other members of the Class suffered harm. Until the final disclosure, on May 7, 2019, each of Mylan's disclosures described below only partially revealed the relevant truth, and Defendants accompanied each disclosure with additional false and misleading information that maintained the artificial inflation in the price of Mylan's stock. As such, the full amount of inflation was not removed until after the final disclosure on the last day of the Class Period.

330. Specifically, Defendants' materially false and misleading statements misrepresented Mylan's compliance with FDA regulations, including those governing CGMP and data integrity. When the relevant truth regarding Defendants' prior misrepresentations and

omissions of material fact were disclosed to investors, the price of Mylan securities fell significantly. As a result of these disclosures, the price of Mylan common shares declined by approximately 50%, from a closing price of $43.15 per share on February 16, 2016, the first day of the Class Period, to a closing price of $21.53 per share on May 7, 2019, the last day of the Class Period.

331. The disclosures that partially corrected the market price of Mylan's common stock and reduced the artificial inflation caused by Defendants' materially false and misleading statements and omissions are detailed below:

Date	Corrective Event	Closing Stock Price	Change from Previous Day's Close
June 27, 2018	*Bloomberg* reported that, in the spring of 2018, the FDA conducted a five-week inspection of the Morgantown facility and issued a Form 483 listing 13 significant deficiencies in Morgantown's operations.	$36.33	-$1.12
August 8, 2018	Mylan disclosed that, following the FDA's inspection, the Company undertook a restructuring and remediation program at Morgantown that included the discontinuation of certain products and negatively impacted production, supply, and operations. Mylan also disclosed approximately $87 million in expenses related to the Morgantown restructuring and remediation and a $2.8 billion decline in total revenue.	$36.61	-$2.62
February 26, 2019	Mylan disclosed a 5% and 4% decline of total quarterly and yearly revenues; a 16% decline in North American segment net sales, driven by the Morgantown remediation; the discontinuation of 250 products; and $258 million in remediation costs.	$26.01	-$4.61

Date	Corrective Event	Closing Stock Price	Change from Previous Day's Close
May 7, 2019	Mylan disclosed losses for the first quarter of 2019 due to costs associated with the Morgantown remediation, including 7% and 15% declines in revenue and earnings-per-share.	$21.53	-$6.73

332. It was entirely foreseeable to Defendants that their materially false and misleading statements and omissions regarding CGMP and data integrity violations at the Morgantown facility would artificially inflate the price of Mylan's common stock. It was also foreseeable to Defendants that the revelation of the relevant truth about Mylan's CGMP and data integrity violations at the Morgantown facility would cause the price of the Company's securities to fall as the artificial inflation caused by Defendants' misstatements and omissions was removed. Thus, the economic losses (i.e., damages suffered by Lead Plaintiff and other members of the Class) were a direct, proximate, and foreseeable result of Defendants' materially false and misleading statements and omissions of material fact, which artificially inflated the price of the Company's common stock, and the subsequent significant decline in the value of the Company's common stock when the relevant truth was revealed.

IX. CLASS ACTION ALLEGATIONS

333. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons and entities who purchased or otherwise acquired the publicly traded common stock of Mylan between February 16, 2016 and May 7, 2019, inclusive (the "Class Period"). Excluded from the Class are Defendants and their families, directors, and officers of Mylan and their families and affiliates.

334. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to

the parties and the Court. As of the end of the Class Period, Mylan had approximately 514 million shares of stock outstanding, owned by at least hundreds or thousands of investors.

335. Questions of law and fact common to the members of the Class, which predominate over questions which may affect individual Class members, include:

(a) Whether Defendants violated the Exchange Act;

(b) Whether Defendants misrepresented material facts;

(c) Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) Whether Defendants knew or recklessly disregarded that their statements and/or omissions were false and misleading;

(e) Whether Defendants' misconduct impacted the price of Mylan securities that are a part of the defined Class;

(f) Whether Defendants' misconduct caused the members of the Class to sustain harm; and

(g) The extent of harm sustained by Class members and the appropriate measure of harm.

336. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained harm from Defendants' wrongful conduct.

337. Plaintiff will adequately protect the interests of the Class and has retained counsel experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

338. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

X. PRESUMPTION OF RELIANCE

339. At all relevant times, the market for Mylan common stock was efficient for the following reasons, among others:

(a) Mylan stock met the requirements for listing, and was listed and actively traded on NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Mylan filed periodic public reports with the SEC and NASDAQ;

(c) Mylan regularly and publicly communicated with investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Mylan was followed by several securities analysts employed by major brokerage firm(s) who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firm(s). Each of these reports was publicly available and entered the public marketplace.

340. As a result of the foregoing, the market for Mylan common stock promptly digested current information regarding Mylan from all publicly available sources and reflected such information in the price of Mylan stock. Under these circumstances, all purchasers of Mylan stock within the defined Class during the Class Period suffered similar injury through their purchase of Mylan stock at artificially inflated prices, and the presumption of reliance applies.

341. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are grounded on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information regarding Mylan's compliance with FDA regulations—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important

in making investment decisions. Given the importance of Mylan's compliance with FDA regulations, as set forth above, that requirement is satisfied here.

XI. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR

342. Mylan's "Safe Harbor" warnings accompanying any forward-looking statements issued during the Class Period were ineffective to shield those statements from liability.

343. Defendants are also liable for any false or misleading forward-looking statements pleaded in this Complaint because, at the time each such statement was made, the speaker knew the statement was false or misleading, and the statement was authorized and/or approved by an executive officer of Mylan who knew that the statement was false, and/or the statement omitted material adverse information whose disclosure was necessary to render the statement not misleading. None of the historic or present tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, because they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to, or stated to be dependent on, those historic or present tense statements when made.

XII. CLAIMS BROUGHT PURSUANT TO THE EXCHANGE ACT

FIRST CLAIM FOR RELIEF

For Violation of Section 10(b) of the Exchange Act and SEC Rule 10b-5 Thereunder (Against All Defendants)

344. Plaintiff repeats, incorporates, and realleges each and every allegation set forth above as if fully set forth in this Complaint.

345. During the Class Period, Defendants Mylan, Bresch, Malik, and Parks carried out a plan, scheme, and course of conduct which was intended to and, throughout the Class Period,

did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged in this Complaint; and (ii) cause economic harm to Plaintiff and other members of the Class.

346. Defendants Mylan, Bresch, Malik, and Parks: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and/or (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

347. Defendants Mylan, Bresch, Malik, and Parks, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the Company's financial well-being, operations, and prospects.

348. During the Class Period, Defendants Mylan, Bresch, Malik, and Parks made the false statements specified above, which they knew or recklessly disregarded to be false or misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

349. Defendants Mylan, Bresch, Malik, and Parks had actual knowledge of the misrepresentations and omissions of material facts set forth in this Complaint, or recklessly disregarded the true facts that were available to them. Defendants Mylan, Bresch, Malik, and Parks engaged in this misconduct to conceal Mylan's true condition from the investing public and to support the artificially inflated prices of the Company's stock.

350. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they purchased Mylan stock and were harmed when the truth about Mylan negatively

impacted the price of those securities. Plaintiff and the Class would not have purchased Mylan stock at the prices they paid, or at all, had they been aware of the truth about Mylan.

351. As a direct and proximate result of Defendants Mylan, Bresch, Malik, and Parks's wrongful conduct, Plaintiff and the other members of the Class suffered harm in connection with their respective purchases of the Company's stock during the Class Period.

352. By virtue of the foregoing, Defendants Mylan, Bresch, Malik, and Parks violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

SECOND CLAIM FOR RELIEF

For Violation of Section 20(a) of the Exchange Act (Against the Officer Defendants)

353. Plaintiff repeats, incorporates, and realleges each and every allegation set forth above as if fully set forth in this Complaint.

354. The Officer Defendants acted as controlling persons of Mylan within the meaning of Section 20(a) of the Exchange Act. By virtue of their high-level positions, participation in, and/or awareness of the Company's operations, direct involvement in the day-to-day operations of the Company, and/or intimate knowledge of the Company's actual performance, and their power to control public statements about Mylan, the Officer Defendants had the power and ability to control the actions of Mylan and its employees. By reason of such conduct, the Officer Defendants are liable pursuant to Section 20(a) of the Exchange Act.

XIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensation to Plaintiff and other Class members against all Defendants, jointly and severally, for all harm sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

D. Awarding such equitable/injunctive or other further relief as the Court may deem just and proper.

XIV. JURY DEMAND

Lead Plaintiff demands a trial by jury.

Dated: November 13, 2020

Respectfully submitted,

/s/ Katherine M. Sinderson

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APPENDIX
Former Employee Key

FE	Tenure	Relevant Position(s) or Role(s)
1	Pre-Class Period – May 2017	Quality Control; Technical Area Lead, Packaging
2	Pre-Class Period – April 2018	Quality Assurance Specialist
3	2016 – 2019	Quality Control and Validation Chemist
4	Pre-Class Period – mid-2016	Quality Control Chemist
5	Pre-Class Period – November 2016	Global Quality Compliance Manager
6	Pre-Class Period – mid-2018	Lead Financial Analyst
7	Pre-Class Period – November 2018	Quality Assurance Supervisor
8	2016-2018	Technical Area Lead, Manufacturing

CERTIFICATE OF SERVICE

On November 13, 2020, I caused the foregoing document to be filed with the Clerk of Court by using the Court's electronic filing system, which sent notice to all counsel of record.

/s/ Katherine M. Sinderson
Katherine M. Sinderson